Cross-Cultural Adaptation of a Child Oral Health-Related Quality of Life Measure

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ABSTRACT

Introduction and background: Oral health-related quality of life (OHRQoL) marks a shift in the perception of health from the mere absence of disease and infirmity to complete physical, mental and social wellbeing. The impact of both general and oral health on quality of life has received increasing attention in recent years. OHRQoL assessments are used in oral health research, surveys and studies evaluating the outcome of oral care. If researchers have no appropriate health-related quality of life (HRQoL) measure in their own language, they have two options: to develop a new measure or to modify a measure that has previously been validated in another language, in a process known as cross-cultural adaptation.

Aim of thesis: To assess the validity and reliability of Arabic versions of two OHRQoL questionnaires – the Child Perceptions Questionnaire for 8-10-year-olds (CPQ8-10) (Jokovic et al, 2003) and Parental Perceptions of Child Oral Health-related Quality of Life (P-CPQ6-14) (Jokovic et al, 2004) among Saudi children aged 8-10 years and their parents respectively.

Method: Culturally equivalent Arabic forms of the CPQ8-10 and P-CPQ6-14 were created following the guidelines of Guillemin et al (1993). Seventy-five children aged 8 to 10 years and their parents attending three dental clinics in Alhasa, Saudi Arabia, completed the questionnaires. A further 75 children and their parent from a dental clinic in London and a community clinic were recruited in England.

Results: The score means and psychometric properties were similar to the original development scale in the parental and child questionnaires obtained by Jokovic et al (2003) and Jokovic et al (2004) respectively. The Saudi version of the CPQ8-10 also showed good internal consistency for all subscales and the total scale (all Cronbach's alpha > 0.50). There were no significant differences in OHRQoL for children in the two national samples for the total scale and subscales ($p > 0.05$), except for social wellbeing ($p = 0.018$). Comparison of Saudi and English parents found no significant differences on the total scales or any subscales (all $p > 0.05$).

Conclusion: The Arabic versions of the CPQ8-10 and Parental/caregiver Perceptions Questionnaire developed for the study demonstrate cross-cultural equivalence according to the criteria provided by Guillemin et al (1993). The Arabic version of the CPQ8-10 also shows good internal consistency and discriminant validity. In order to assess the change of oral health status and quality of life over time, a prospective study with appropriate sample size is recommended.

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ABBREVIATIONS

COHIP	Child Oral Health Impact Profile
COHRQoL	OHRQoL in Children
CPQ8-10	Child Perceptions Questionnaire for 8-10 year-olds
CPQ11-14	Child Perceptions Questionnaire for 11-14 year-olds
DC	Dental centre
DIDL	Dental Impact on Daily Living
DIP	Dental Impact Profile
DMFS	decayed/missing/filled surface
DMFT	Decayed, missing and filled teeth
ECOHIS	Early Childhood Oral Health Impact Scale
GOHAI	General / Geriatric Oral Health Assessment Index
HRQoL	Health-related quality of life
ICC	Intraclass correlation coefficient
KFHH	King Fahad Hospital Hofuf
MOH	Ministry of Health
OHIP	Oral Health Impact Profile
OH-QoL	Oral Health Quality of Life Inventory
OH-QoL-UK	UK Oral Health Quality of Life Inventory
OIDP	Oral Impacts on Daily Performance
OHRQoL	Oral health-related quality of life
PHCC	Primary Health Care Centre
PPQ6-14	Parental Perceptions of Child Oral Health-related Quality of Life
P-CPQ	Parental/caregiver Perceptions Questionnaire
SIDD	Social Impacts of Dental Disease
QoL	Quality of life
SD	Standard deviation
SOHSI	Subjective Oral Health Status Indicators
WHO	World Health Organization

1. INTRODUCTION

1.1. Thesis structure and outline

The aim of this thesis is to describe the cross-cultural validation of an Arabic version of the child oral health-related quality of life questionnaire (CPQ8-10) and the parental perception of oral health-related quality of life questionnaire (P-CPQ6-14) in Saudi Arabia.

This first chapter offers a description of the demographic and oral health status of the Saudi population. Chapter two presents a review of literature on oral health-related quality of life (OHRQoL) in adults and children, which describes previous studies that have been conducted in this field and which are related to my thesis. There follows a review of literature on cross-cultural adaptations of health-related quality of life (HRQoL) measures in Chapter three. Chapter four then describes the process of cross-cultural validation of an Arabic version of the questionnaire. Chapter five reports a study of the psychometric properties of the Arabic version, and then Chapter six presents findings concerning the validation and development of the Arabic version. Chapter seven brings together and discusses the findings, relates these to the findings of previous studies and makes recommendations for future research in this field.

1.2. Demographic structure of Saudi Arabia

Saudi Arabia was established and united by King Abdulaziz in 1932, since which time the government has sought to modernise the country. The Kingdom occupies two million square kilometres, four-fifths of the Arabian Peninsula, and has a population of 20 million. Saudi Arabia is divided into five main areas: the Central, Northern, Southern, Eastern and Western regions. It borders Jordan to the north, Iraq to the north and north-east, Kuwait, Qatar, Bahrain and the United Arab Emirates to the east, Oman to the south and south-east, and Yemen to the south, with the Persian Gulf to its north-east and the Red Sea to its west (Figure 1.1).

Figure 1.1: Map of Saudi Arabia

Saudi Arabia holds an exceptional position in the Islamic world, as the guardian of the two holiest places of Islam, in Mecca and Medina. Annually, about two million Muslims from all over the world go to Mecca and Medina for the major pilgrimage (Hajj) and the minor pilgrimage (Umra) (MOP, 2005).

Oil is the major source of foreign exchange, contributing 81% of government revenue. The labour force is distributed as follows: government service 55%, industry 10%, agriculture 13%, construction 20% and oil 2%. Two large oases, Hofuf and Qatif, support substantial agricultural production. The climate is dry and hot: the highest temperatures in the world are recorded in Saudi Arabia during the summer, while the winters are mild with little rainfall (Sebai, 1980).

The demographic characteristic of Saudi Arabia are similar to those of many Arab countries. The average rate of population growth is about 3% a year and fertility rates are high. The demographic structure is characterized by the youthfulness of the population: those aged 15 years or under account for almost half of the population, while in 1992 about 3.4% population was aged over 60 years. The rate of economic activity is low, ranging from 22% to 32% of total population. While the population

(23,520,000) is growing at a rate of 3% or more per year, the mortality rate is 14.1 per 1000. Life expectancy at birth for males and females is 68.4 and 73.9 years respectively. The child mortality per 1000 is 30 for males and 25 for females, while respective adult mortality rates are 192 and 112 per 1000 respectively (MOH, 2009).

Saudi Arabia has undergone considerable development in field services and medical education. The rapid expansion of health services has increased the demand for health personnel. The Ministry of Health (MOH) is the main agency responsible for the provision of healthcare to the population in Saudi Arabia. However, several other agencies sponsor health facilities which care primarily for employees and their dependents. These include the Ministries of Defence, Interior and Education, the National Guard and several large companies such as Saudi Aramco, the largest oil company in Saudi Arabia (MOH, 2009).

1.3. Oral health in Saudi Arabia

The Saudi oral healthcare system, like those of many other developing countries, is characterised by independent professions with government regulation. Dental health awareness in Saudi Arabia started late. During the twentieth century, dental practice was largely conducted by traditional therapists and by uncertified and unlicensed practitioners from neighbouring countries, especially during the Hajj season. Oral healthcare systems focus on the prevention of oral diseases, through education and services provided in dental clinics and in community settings. The structure is headed by the MOH, above local regions which run primary healthcare and secondary and tertiary centres. The dental care system covers diagnosis, prevention and treatment, including fillings, prostheses and oral surgery (MOH, 2009).

The dental schools in Saudi Arabia provide important community services for all age groups to receive dental treatment. The first college of dentistry was established in 1973 in Riyadh, followed by the dental school of King Abdulaziz University in Jeddah in 1985. There were then the College of Dentistry at King Faisal University in the Eastern region, which was opened in 2002, the College of Dentistry at King Khalid University in 2004 and the College of Dentistry at Qassim University, which was established and accepted students in 2008. In response to an increase in population and growing awareness of the importance of dental care, private colleges

of dentistry were opened in Riyadh in 2003 and in Jeddah in 2004 (Shaker and Babgi, 2009).

The most prevalent oral diseases in Saudi Arabia are dental caries and periodontal disease, which a number of reports have shown to affect various age groups (Al-Shammary et al, 1991). For example, the indices of decayed, missing and filled teeth (dmft) for 5 years and 12 years were 9.2 and 7.1 respectively. The incidence of cleft lip and palate in 1994 was about 1,9 per 1000 births. According to the World Health Organisation, about 20.4% of 65-year-olds were edentulous. Sugar consumption in 1997, 2000 and 2002 was 29.8, 26.9 and 31.2 respectively (WHO, 2003). Dental erosion is a common risk factor in both primary and permanent teeth (Al-Majed et al, 2002; Al-Malik et al, 2002). A recent study of caries prevalence and its relation to water fluoridation levels among schoolchildren found that the prevalence of caries was 91.2% in Riyadh and Qaseem, where the mean DMFT values were 5.06 and 4.53 respectively (Al-Dosari et al, 2004). A retrospective study of the emergency and primary dental care treatment provided at King Saud University College of Dentistry for the years 1987 and 1988 found that the total numbers of patients were 17,653 and 16,221 respectively. Restorative treatment constituted the major category, followed by consultations, screening and extractions, while periodontal and prosthetic treatment were given much less often than other categories of dental care (Rahmatulla et al, 2004). This may be due to an insufficiency in oral health prevention programmes. A study of 500 patients aged between 18 and 50 years old found that about half used no oral health care. These who did take care of their oral health used toothpaste and miswak sticks. The study also showed that the most effective source of oral health education was television (Al-Ansari, 2007)

2. ORAL HEALTH-RELATED QUALITY OF LIFE

2.1. Introduction

The key issue in the conception of HRQoL and accordingly of OHRQoL is the shift in the perception of health from merely the absence of disease and infirmity to complete physical, mental and social wellbeing, in line with the definition of health by the WHO (1948). It is now widely accepted that health assessment should include the measurement of physical, social and psychological functions and of the quality of life (QoL) (Waters et al, 2006). OHRQoL has components such as function, pain, psychological components and social aspects (Locker, 1988; Power and Kuyken, 1998). The impact of both general and oral health on the quality of life has received increasing attention in recent years (Anderson et al, 1993). OHRQoL assessments are used in oral health research, surveys and studies evaluating the outcome of oral care (McGrath and Bedi, 2002; Locker et al, 2004). It is also recommended that when assessing oral health outcomes and oral health need, researchers should include the psychological impact of oral health (Buck and Newton, 2001).

OHRQoL measures have three broad characteristics. First, they could be used for political purposes, to demonstrate the effects of oral disorders to policy makers. Second, they could have theoretical value in developing and testing models of oral health and general health. Thirdly, the measures should be put to practical use in research to best meet needs for planning and evaluating treatment of individuals (Locker, 1996). Furthermore, OHRQoL is an essential factor in evaluating the outcomes of preventive and therapeutic programmes planned to improve the oral health status of the population (Al Shamrani, 2006; Allison et al, 1999).

2.2. Definition of quality of life and oral health-related quality of life

The WHO (1997) defines quality of life as “an individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns”. This global definition reflects a subjective evaluation, embedded in culture, society and environment. It does not seek to assess diseases or conditions but rather their effects and those of health interventions. It is a broad concept, affected in a complex way by people’s physical health, psychological state, level of independence, social

relationships and relationships to the salient features of their environment (Bond and Corner, 2004; Wallander and Schmitt, 2001).

The term OHRQoL has no strict definition, but there is general agreement that it is a multidimensional concept (Locker, 1988). The definitions which have been adopted vary from simple to more rigorous. One of the simpler ones is that reported by the United States Surgeon General in Oral Health, which defines OHRQoL as "a multidimensional construct that reflects people's comfort during eating, sleeping and engaging in social interaction with respect to their oral health" (NIH, 2000). On the other hand, a more complex view defines it as "an individual's assessment of how the following affect his or her well-being: functional factors, social factors, psychological factors and experience of pain in relation to oro-facial concerns" (Locker, 1998).

A multidimensional model of OHRQoL based on HRQoL models has been proposed by Patrick and Erickson (1993). It includes the absence of impairment, disease or symptoms; the appropriate physical functioning associated with chewing, swallowing and absence of discomfort and pain; the emotional functioning associated with smiling; the social functioning associated with normal roles; the perception of excellent oral health; satisfaction with oral health; and the absence of social or cultural disadvantage due to oral health status (Gift and Atchison, 1995).

2.3. Existing measures of adult OHRQoL

Most OHRQoL measures have been developed according to Locker's (1988) multidimensional model, which provides a scientific basis for understanding oral disorders and their consequences. Based on the WHO classification of impairment, disability and handicap, it seeks to capture most of the functional and psychosocial outcomes of dental and oral disease. Locker's model states that oral disorder has five consequences: impairment, functional limitation, pain/discomfort, disability and handicap. All of these are consecutively related to each other, as shown in Figure 2.1.

Several socio-dental or OHRQoL indicators have been developed and used for assessing oral wellbeing and to describe oral impacts on people's quality of life (Slade, 1997). In general, most indices of OHRQoL measure how oral conditions

disrupt normal social role functioning and lead to major changes in behaviour, such as inability to work, attend school, or undertake parental or household duties (Locker, 1998; Weintraub JA (1998).

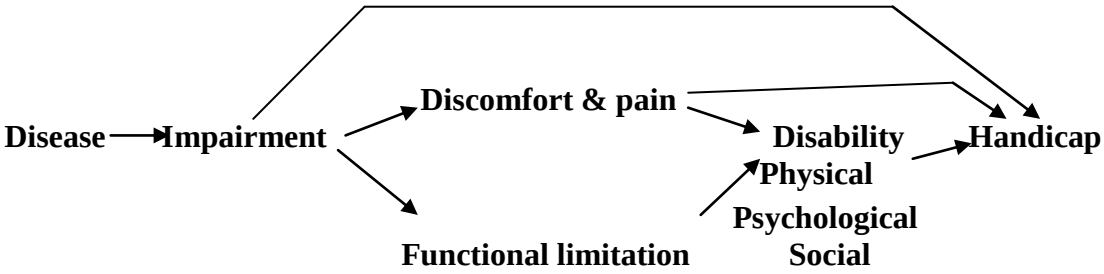

Figure 2.1: Conceptual model for measuring oral health (Locker, 1988)

Most of the OHRQoL indicators developed so far measure either the effect or the impact of oral health on quality of life, while others may measure the effect and impact together. The former refers to the physical, psychological and social effects of oral health, while impact refers to daily activities, ability to chew, talking to people and overall quality of life (Slade and Spencer, 1994). The effect and impact domains of oral health are better assessed using OHRQoL measures, rather than the Clinical Disease Measure (Slade et al, 1998; Okunseri et al, 2005).

2.3.1. OHRQoL measures

The original items comprising the OHRQoL tools were selected from existing measurements that assessed the impacts of oral health on quality of life. These are: three items concerned with the possible effects of oral disease (responses scored on a six-point scale ranging from “all of the time” to “none of the time”), two items assessing oral discomfort and two items evaluating eating problems with a yes/no response format. Dental pain was also assessed by asking how much pain or distress was caused by the respondent’s teeth or gums in the last three month (1 = not at all to 5 = a great deal) (Bowling, 1997). The OHRQoL index was developed with data from the Department of Veterans Affairs Normative Aging Study/ Dental Longitudinal Study (Humphris et al, 2005). The mean age and standard deviation (SD) of the participants were 67.3 and 7.7 respectively. The results show a strong association between the items (Cronbach’s alpha = 0.83). However, the correlation

between OHRQoL and general life satisfaction and self-related health was small, but in the expected direction. Thus the tool was found to have generally good psychometric properties and the association with external criteria was in the expected direction (Kressin et al, 1996).

2.3.2. Social Impacts of Dental Disease

The Social Impacts of Dental Disease **(**SIDD) instrument was one of the first socio-dental indicators, which were developed in 1980s. It combines models of dental disease and health behaviour in order to create a framework to assess clinical and psychosocial features. The model represents oral health status and treatment needs, which are influenced by three dimensions: vulnerability, motivation and prevention. The vulnerability dimension is related to the client's socio-economic background, dental history and access to dental services, while the motivational dimension is related to belief, attitudes and concerns. Finally, the preventive dimension is related to current dental practice self-care measures and promotes dental health (Sheiham et al, 1997).

The social and psychological impact of dental diseases are placed in five categories of impact: eating restriction, communication restriction, pain, discomfort and aesthetic dissatisfaction. The total impact score is derived by summing the score of all five categories. Cushing (1986) applied SIDD to large randomly selected samples in the north and south of England, finding a statistically significant correlation between dental appearance and communication restriction; he also reports good test-retest reliability. Generally, SIDD can be used as an initial tool to measure dental impacts (Cushing et al, 1986).

2.3.3. General / Geriatric Oral Health Assessment Index

The General (originally Geriatric) Oral Health Assessment Index (GOHAI) provides an index of the impact of oral disorders, which is calculated by assigning an overall score to indicate the extent of a range of functional and psychosocial consequences. The GOHAI consists of twelve items, such as "How often do you feel uncomfortable eating in front of people because of problems with your teeth or dentures?", with responses such as: 0 = never, 1 = seldom, 2 = sometimes, 3 = often, 4 = very often, 5 = always. The response codes are summed across the twelve items to give an overall

score between 0 and 60. The GOHAI was constructed to assess the psychosocial impacts of oral diseases and to evaluate the outcome or change in the effectiveness of dental treatment. It was first tested on a sample of 87 older people. A revised version of the instrument was administered to a sample of 1755 adults in Los Angeles; the original pretest contained 36 items. The researchers found that the GOHAI had an acceptable reliability and validity (Cronbach's alpha = 0.79). Results also showed that people with natural teeth had higher GOHAI scores and fewer problems with limitations on foods that could be eaten and on chewing (Atchison, 1997). A comparable measurement was also found in SIDD (Cushing et al, 1986) and the Subjective Oral Health Status Indicators (Locker and Miller, 1994).

A number of studies have been undertaken using the GOHAI. For instance, Dolan et al. (1990) used it to evaluate the effectiveness of geriatric nurse practitioner intervention in a sample of 331 older adults, reporting a mean score and SD of 53.1 and 7.2 respectively. Another study used a sample of 299 UCLA dental school patients to assess the effectiveness of the FDA Guidelines in Dental Radiography. The researchers found mean and SD GOHAI scores of 47.0 and 8.34 respectively (Marcus et al, 1996). When Tourville et al (1996) used the index to assess the effectiveness of dental care, they found that the GOHAI score for the controls (n=353) was 54.1, while for the experimental group (n=406) it was 53.6.

Tubert-Jeannin et al (2003) assessed the validity of a French version of GOHAI comprising 12 items based on translation and back-translation of the original instrument. After piloting and minor modification, the French version was administered to a group (n=260, age=18-24) of low income persons. The results showed that it had high internal consistency; item scale correlation varied between 0.40 and 0.78; Pearson's correlation coefficient was 0.87; and there were significant relationships between the GOHAI and most objective measures of dental status. It was concluded that the French version of GOHAI had acceptable psychometric properties. Another study, conducted in Saudi Arabia on 156 elderly patients, used the 12-item GOHAI after translation and back-translation. The researchers found that the mean and SD of GOHAI were 32.1 and 12.2 respectively, while reliability and validity were excellent, with Cronbach's alpha of 0.93, intraclass correlation coefficient (ICC) of 0.95 and kappa coefficient values for individual items varying between 0.42 and 0.71 (Atieh, 2008).

2.3.4. Dental Impact Profile

The Dental Impact Profile (DIP) measurement contains 25 items using the format "Do you think your teeth or dentures have a good (positive) effect, a bad (negative) effect or no effect on your eating?" These are subdivided into four scales (eating, health/ wellbeing, social relations and romance), then the overall profile score is calculated as the proportion of positive or negative responses among all answers. The DIP is a self-reporting instrument and can be applied to individuals or a population. In pilot and population studies, the relationship of the subscale items to the subscale scores varied between 0.68 and 0.86, while Cronbach's alpha was 0.93 and 0.85 respectively (Slade, 1997). This index allows a respondent to indicate whether a problem is functional, such as difficulty in chewing, or a social consequence, such as avoiding company with others. The hierarchy of outcomes is based on the WHO classification of impairments, disabilities and handicaps (WHO, 1980) and Locker's theoretical framework for measuring oral health. The advantage of the DIP are that it is brief, easy and simple to conduct, measures both positive and negative impacts, influenced by ethnic and cultural status, is self reporting and can be assessed for impact on oral health services and health promotion. However, it does not measure disability or dysfunction. There is a subscale to do so, but it is not widely used and in order to obtain an acceptable result it should be administered by an interviewer (Slade, 1997).

2.3.5. Oral Health Impact Profile

The Oral Health Impact Profile (OHIP) is an index comprising 49 items divided into seven theoretical domains: functional limitation, pain, psychological discomfort, physical disability, psychological disability and handicap. An example of an OHIP item is: "Have you had to interrupt meals because of problems with your teeth, mouth or dentures?" The response format is 0 = never, 1 = hardly ever, 2 = occasionally, 3 = fairly often and 4 = very often. The frequency of impacts is calculated by summing the reported negative impacts across the 49 items. The main advantage of this instrument is that the items were derived from a representative patient group rather than being invented by dental research workers. It reflects the concerns of patients and is considered to be the most sophisticated measure of oral health (Locker, 1998). When the OHIP instrument was tested among 122 adults aged

60 years and over in Adelaide, it was found to have good internal reliability: Cronbach's alpha ranged from 0.70 to 0.83. It was then administered to 46 people in order to assess intraclass correlation coefficients; test-retest reliability ranged from 0.42 to 0.77 (Locker, 1988). Another study was conducted in Ontario, Canada on adults aged 50 years and over. This time, Cronbach's alpha ranged between 0.80 and 0.90 (Locker and Slade, 1993).

OHIP was also used with people of different cultures and languages after appropriate cross-cultural adaptation for such countries as Germany (John et al, 2002; Van de Meulen et al, 2008), Spain (Lopez and Baelum, 2006), Hungary (Szentpétery et al, 2006) and Japan (Yamazaki et al, 2007). The researchers found that OHIP had adequate psychometric properties, including discriminant validity, internal consistency and test-retest reliability, to be used for the assessment of oral health-related quality of life in both cross-sectional and longitudinal studies.

The short version of OHIP, comprising 14 items derived from the 49-item OHIP, appeared to have good validity and reliability properties (Slade, 1997). The short form has also been used with different languages and cultures after cross-cultural adaptation, for example in Canada (Locker and Allen, 2002) and Scotland (Fernandes et al, 2006). It has also been used in a Hebrew version (Kushnir et al, 2004), on elderly Japanese subjects (Ikebe et al, 2004) and in Brazil (De Oliveira and Nadanovsky, 2005). Researchers have found all these short versions to have good psychometric properties with valid and reliable results in those countries.

2.3.6. Subjective Oral Health Status Indicators

The Subjective Oral Health Status Indicators (SOHSI) was developed by David Locker in Canada in 1997 to describe the functional, social and psychological outcome of oral disorders and conditions. The SOHSI instrument, which has been used in adult populations in Canada and in the UK, is based on the International Classification of Impairments, Disabilities and Handicaps (WHO, 1980). Initially, it consisted of four indexes and one scale, but now includes six items on chewing, three items on the ability to speak, nine addressing oral and facial pain and ten concerned with other oral symptoms. The social and psychological impacts are assessed by four subscales: three items for eating problems, four for communication/social relations,

six items for other limitations and a two-item subscale for worry and concern about oral health (Slade, 1997).

A study was conducted on a randomly selected population aged 18 years and over, using a mail questionnaire administered to a sample of 553 subjects, of whom 156 completed it twice. The index was found to be sensitive for all adults; Cronbach's alpha for psychosocial scales ranged from 0.70 to 0.87. The validity was also assessed and found to be significant in the expected direction (Locker and Miller, 1994). The validity and reliability were also measured in the UK, where a study of two groups aged 65 years and over found that test-retest reliability ranged between 0.56 and 0.99, while Cronbach's alpha for psychological impact scales ranged between 0.81 and 0.90 (Tickle et al, 1996, cited by Slade, 1997).

The concurrent validity of SOHSI with the OHIP indicator was also assessed from a three-year follow up; correlations were found to be significant and moderate to strong (Slade and Spencer, 1994). A longitudinal study was also used to assess the sensitivity of SOHSI. A significant association was found and the effect, which was moderate to strong, ranged between 0.38 and 0.87 (Locker, 1997). Generally, SOHSI has the advantages of being based on a cohort study, reliable, valid and sensitive to change over time. However, it is not suitable for measuring clinical outcomes or evaluating clinical studies (Slade, 1997).

2.3.7. Dental Impact on Daily Living

The Dental Impact on Daily Living (DIDL) instrument consists of 36 items divided into five scales: comfort, appearance, pain, performance and eating restrictions. Impacts for each statement are coded as follows: +1 = positive impacts, 0 = impacts not considered and -1 = negative impacts. In order to calculate an overall score, scores within each dimension are first calculated by multiplying the summed dimension responses by the dimension weight. The weighted dimensions scores are then summed to give a DIDL score (Leao and Sheiham, 1996). DIDL has been tested and validated on 662 people of ages ranging between 35 and 44 years in Brazil. Two socio-demographic factors, sex and social class, were assessed. A significant association was found between oral status and socio-psychological measures; the

researchers conclude that social and psychological measures should be tested during dental needs assessment (Leao and Sheiham, 1995).

DIDL is different from other socio-dental indicators that create an impact score for each dimension. It is also different in that weighting is assigned by every individual person through an easy-to-use system of a sliding arrow that the subject shifts along a scale. Furthermore, the DIDL score estimates total oral impacts. Generally, this is a flexible means of analyzing individual items, dimensions and total score (Slade, 1997).

2.3.8. The Oral Health Quality of Life Inventory

The Oral Health Quality of Life Inventory **(**OH-QoL) is a dental-specific measure comprising 15 items which assess oral health and personal satisfaction. It was developed by the National Institute of Health in Texas as a subproject to measure the quality of life related to oral health. Each OH-QoL item is rated on two dimensions: Importance and Satisfaction. Importance responses are coded as -1, 1 and 2 for not at all, somewhat and very important respectively. Satisfaction responses are coded as -2, -1, +1 and +2 for unhappy, somewhat unhappy, somewhat happy and happy respectively. The OH-QoL score for each item is given by importance multiplied by satisfaction and the overall score is the mean value of the answered items (Slade, 1997).

The OH-QoL was evaluated by means of the Oral Health Quality of Life Interview. One hundred adult patients aged between 20 and 84 years were interviewed at the University of Texas Health Science Center Dental Clinic; data from 98 patients was usable. The results suggest that OH-QoL has an acceptable internal consistency and validity, with Cronbach's alpha = 0.84 and correlation (r) ranging from -0.23 to -0.53. All correlations were significant at $p < 0.05$ (Frisch et al, 1992).

2.3.9. Oral Impacts on Daily Performance

The Oral Impacts on Daily Performance (OIDP) instrument measures the impact of oral problems on 8 daily tasks: eating and enjoying food, speaking and pronouncing clearly, cleaning teeth, sleeping and relaxation, smiling, laughing and showing teeth without embarrassment, maintaining usual emotional state without being irritable,

carrying out major work or a social role and enjoying contact with other people. The possible responses corresponding to the frequency of impact range from 0 = never affected in the past 6 months to 5 = every/ nearly every day for the past last 6 months. The respondents are also asked to rate the severity of the impact on a scale of 0 = none to 5 = very severe. The overall score is then calculated by multiplying frequency by severity for each item (Adulyanon and Sheiham, 1997).

Studies were conducted in Uganda (Astrøm and Okullo, 2003) and Norway (Astrøm et al, 2006) to assess the validity and reliability of OIDP after cross-cultural adaptation. The researchers found that OIDP had acceptable psychometric properties when used to measure oral health and quality of life in both samples. Three further studies were conducted in Tanzania (Kida et al, 2006; Masalu and Astrøm 2003), Iran (Dorri et al, 2007) and Korea (Jung et al, 2008). All versions showed good psychometric properties, with acceptable validity and internal consistency reliability. Furthermore cross-sectional epidemiological study was recruited to evaluate a modified version of the OIDP in elderly people (65 years or older) in Britain and Greece, it was conclude the modified OIDP is valid and reliable measure of OHRQoL in elderly people for both countries (Tsakos et al, 2001).

2.3.10. UK Oral Health-Related Quality of Life Measure

A British version of OH-QoL (OH-QoL-UK) consisting of 16 items was developed for use in the general UK population. The instrument is easy to apply and shows good psychometric properties which take account of both oral and general quality of life. It has been used and assessed in multiple studies including some with cross-sectional and longitudinal designs (McGrath and Bedi, 2001; McGrath and Bedi, 2004).

In a study to assess the reliability and validity of the OH-QoL-UK instrument, the questionnaire was distributed to 500 adults. It was found to be a valid and reliable measurement with high internal reliability (Cronbach's alpha = 0.94) (McGrath and Bedi, 2003). OH-QoL-UK was also evaluated in a Brazilian population after translation and back-translation. Psychometric properties including validity and reliability were assessed in a sample of 450. The response rate was 72% and the results show high internal consistency (Cronbach's alpha = 0.96) and good

agreement of each of the items (kappa ranged from 0.57 to 0.87). It was confirmed that the translated OH-QoL-UK measure was applicable to the Portuguese language speakers of the Brazilian population (Dini et al, 2003).

An Arabic version of OH-QoL-UK was also assessed in three Middle Eastern countries (Syria, Egypt and Saudi Arabia) after being translated and back-translated. The instrument was administered to 1,000 adults and its psychometric properties, including construct validity and criterion validity, were measured and found acceptable. The internal reliability was good and high (Cronbach's alpha = 0.90) (McGrath and Bedi , 2003). All of these findings indicate that OH-QoL-UK shows evidence of good cross-cultural adaptation**.**

2.3.11. Summary of measures of OHRQoL for adult

Several measures of oral health related quality of life in adults have been developed. A review of these was undertaken in order to inform an understanding of the process of validation and cultural adaptation of oral health related quality of life measures in dentistry, despite the priory focus of the author's thesis being the measurement of oral health related quality of life in children. To date several measures of OHRQoL in adults have been developed, primarily these have been used in epidemiological research. All have been extensively tested for reliability, internal consistency and validity. Most follow the theoretical framework provided by Locker's Model of Oral Health (Locker, 1988). It is clear that theoretically sound, reliable and valid measures of oral health related quality of life exist for use with adults. However there has been little cross cultural validation of such measures, and what little has been done has tended to focus primarily on translation rather than cultural validation.

2.4. Measures of Oral health-related Quality of Life in Children

Child OHRQoL measures can be used to describe the outcomes of care (Sheiham et al, 1982) and can guide the development of guidelines for evidence-based dentistry (Locker, 1995). Generally, the guidelines for selecting an OHRQoL measure for children should cover multiple criteria, including acceptability to the population, clarity, ease of use and generic definition. The domains should include objective and subjective approaches and perceived importance to the child. In addition, the OHRQoL measure should demonstrate satisfactory psychometric characteristics and

provide a standard for the general population in addition to children in the target group (Cummins, 2000; Lawrence et al, 2007).

Initially, measurement of OHRQoL in children was based on proxy reports by their guardians (Richards and Hemstreet, 1994), but direct OHRQoL measures for children have recently been introduced. These have been developed using standardised approaches to the development of questionnaires, to ensure validity and reliability. The instruments are: OHRQoL in Children (COHRQoL) (Jokovic et al, 2002), Child Oral Health Impact Profile (COHIP) (Broder et al, 2007), Child-OIDP (Gherunpong et al, 2004) and Early Childhood Oral Health Impact Scale (ECOHIS) (Pahel et al, 2007). Although these measures have been applied in Europe and America, they have not been commonly used in non-Western countries; therefore there is a need for research in non-Western countries and precise studies of the impact on children there of OHRQoL.

2.4.1. Child Perceptions Questionnaire for 11-14 year-olds

The Child Perceptions Questionnaire for 11-14 year-olds (CPQ11-14) was developed in Canada (Jokovic et al, 2002). The target group in the study was children aged 11 to 14 years with dental caries, malocclusion and oro-facial disorders. They were recruited from paediatric dentistry and orthodontic clinics at the Faculty of Dentistry, University of Toronto, from the Craniofacial Clinic at the Hospital for Sick Children, Toronto and from the Toronto Public Health Dental Clinics. The CPQ11-14 was constructed following guidance on theory and scale development from Streiner and Norman (1996) and DeVellis (1991).

The development process comprised two stages. First, an initial group of 46 items was developed by a review of available oral health and child health status measures. These encompassed four domains: oral symptoms, functional limitations, emotional wellbeing and social wellbeing. Second, the comprehensive relevance and clarity of these items were assessed by an expert panel composed of 17 health professionals who treated children with oral and oro-facial disorders and 33 parents of child patients with these conditions. Based on their responses and comments, a modified pool of 50 items was developed by writing additional items, excluding items and combining items. These were revised further following in-depth interviews with 11 children. Items for the final questionnaire were selected by means of an item impact

study (Guyatt et al, 1986; Juniper et al, 1996). This identified items according to their frequency and importance to the target population. The participant children from the three clinical groups were then selected. Next, data were collected by means of an item impact questionnaire administered in face-to-face interviews. The children were asked if in the past three months they had experienced the problem described by each item. Those responding positively then rated the importance of the problem on a 4-point scale ranging from 0 = does not bother me at all to 4 = bothers me very much. Finally, the researchers calculated an impact score by multiplying the percentage of children with positive responses by the item's mean importance rating. Items were ranked within the four health domains according to their impact scores, then separate rankings were created for each clinical group. Items that were above the median in each ranking were selected for the final questionnaire.

The resulting CPQ11-14 consists of 37 items structured into four health domains: oral symptoms, comprising six items, functional limitations (nine items), emotional wellbeing (nine items) and social wellbeing (thirteen items). These ask about the previous three months in relation to the child's oral health conditions, the choice of responses being 0, 1, 2, 3 and 4 for 'never', 'once/twice', 'sometimes' and 'every day/ almost every day' respectively. In addition, the questionnaire contains items to elicit global ratings of the child's oral health and the extent to which oral health conditions affect his or her overall wellbeing. These are worded as follows: "Would you say that the health of your teeth, lips, jaws and mouth is…" and "How much does the condition of your teeth, lips, jaws or mouth affect your life overall?" These global rating items have a five-point response format ranging from: 0 = excellent to 5 = poor for oral health and from 0 = not at all to 5 = very much for wellbeing (Jokovic et al, 2002).

The CPQ11-14 was assessed for validity and reliability. The validity testing involved a new sample of 123 children recruited from paediatric dentistry, orthodontic and craniofacial patients in Toronto. The test-retest reliability was assessed in a subgroup of these children (n = 65). It was found that the mean CPQ11-14 scores were highest for oro-facial patients, then orthodontic and paedodontic patients, at 31.4, 24.3 and 23.3 respectively, which confirmed discriminant validity. There were significant associations between the scores and global ratings of oral health and overall

wellbeing, with p-values of < 0.05 and < 0.01 respectively. The Cronbach's alpha and ICC were 0.91 and 0.90 respectively. The researchers concluded that the cross-sectional validity and test-retest reliability of the CPQ11-14 was acceptable (Jokovic et al, 2002).

The validity of the CPQ11-14 was tested independently in a random sample of children (n = 430) aged 12-13 years old in New Zealand (Foster Page et al, 2005). The researchers found that children with greater dental caries and with more severe malocclusions had higher overall CPQ11-14 scores, while those in the top quartile of DMFT distribution had higher CPQ11- 14 scores overall and higher scores for each of the four domains.

Several studies were conducted to assess the impact of malocclusion on quality of life using CPQ11-14 (O'Brien et al, 2006; O'Brien et al, 2007; Locker et al, 2002, Agou et al, 2008; Zhang et al, 2009). The researchers found that CPQ11-14 was valid, reliable and useful for orthodontic trials. They also found that malocclusion in children had a negative impact on OHRQoL compared with that of non-malocclusion children and that different occlusion indices showed variable orthodontic treatment needs. It was recommended that longitudinal analysis with a short form of CPQ11-14 specifically for malocclusion might be more beneficial for future studies.

Indeed, a short form of the CPQ11-14 has been developed and evaluated (Jokovic et al, 2006): in order to facilitate its use in clinical settings and population-based health surveys, it was shortened to 16 and 8 items respectively. Item impact and stepwise regression methods were used to produce each version. The item impact method used data from the CPQ11-14 item reduction study to select the questions with the highest impact scores in each domain. All short forms detected substantial variability in children's OHRQoL. Mean scores on the short forms were found to be higher than the original CPQ11-14 scores ($p < 0.001$). Strongly significant correlations between all short-form scores and the original CPQ11-14 scores were also found (0.81-0.98; $p < 0.001$). Scores on the short-form questionnaires were highest in the oro-facial group and lowest in the paediatric group. All short-form scores were positively correlated with the ratings of oral health and overall wellbeing. The relative validity coefficients were 0.85 to 1.18, while Cronbach's alpha for the scales ranged from

0.71 to 0.83 and correlation coefficients ranged from 0.71 to 0.77. The researchers conclude that the short forms demonstrated excellent criterion and construct validity (Jokovic et al, 2006; Foster Page et al, 2008). A study was also conducted to compare four short-form versions of CPQ11-14 with the full version in a random population children (n=430) aged 12 to 14 years. The children were examined for malocclusion and dental caries. All versions showed acceptable psychometric properties, but the 16-item version had better performance. A factor analysis of the health domains in the full and short forms of the CPQ11-14 were used in a sample of 542 children aged 12 years in Hong Kong. The short form was found to be better fitted in measuring OHRQoL than the full form (Lau et al, 2008).

A study was conducted in the UK to assess the reliability and validity of the CPQ11-14. The research consisted of a cross-sectional questionnaire and clinical study in the orthodontic and paediatric clinics at a dental hospital and one general dental practice. The sample comprised 89 children between 11 and 14 years of age attending for examination. The children were asked to complete the CPQ11-14 and clinical data including caries status, malocclusion, dental opacities and gingivitis were collected. The researchers found that Cronbach's alpha for the total scale was 0.87 and for subscales it ranged between 0.53 and 0.83, which indicated an acceptable internal consistency. The ICC on repeated application of the measure was 0.83, suggesting a high level of agreement. No relationship between clinical and CPQ11-14 data was apparent. The researchers conclude that the CPQ11-14 shows an acceptable reliability and criterion validity in relation to overall life (Marshman et al, 2005). Another study was conducted in South Australia in a general child population, of whom 468 completed the CPQ11-14 questionnaire. It was found to have acceptable internal, construct and discriminant validity, thus confirming that it can be used in measuring OHRQoL in children in the general population (Do and Spencer, 2008).

Cross-cultural adaptations of CPQ11-14 have been tested in different languages and cultures. For example, Goursand et al (2009) and Barbosa et al (2009) found that the Brazilian Portuguese version of the CPQ11-14 was valuable, reliable and applicable to Brazilian children and had satisfactory psychometric properties. Three further studies were conducted in Saudi Arabia (Brown and Al-Khayal, 2006), China (McGrath et al, 2008), Iran (Khadem et al, 2012) and Denmark (Wogelius et al,

2009) after cross-cultural adaptation of CPQ11-14 into Arabic, Chinese, Persian and Danish respectively. Psychometric tests confirmed that CPQ11-14 was valid and reliable to be used in Arabic, Chinese and Danish-speaking children.

2.4.2. Child Perceptions Questionnaire for 8-10 year-olds

Jokovic et al (2004) describe the development of the CPQ8-10 to assess the OHRQoL of children aged 8-10 years (CPQ8-10). Children aged 8-10 years who were free from systematic diseases and/or mental disorders and were fluent in English were recruited as convenience samples from patient populations attending dental public health clinics in York Region, Ontario, Canada and the orthodontic clinic of the craniofacial unit at the Hospital for Sick Children, Toronto. The first group targeted children with dental caries and the second with cleft lip and palate. They were chosen because these are the most prevalent oral health conditions in 8-10 years olds which are expected to have an effect on children's quality of life.

Questions for the CPQ8-10 were selected from the CPQ11-14 based on the child development literature and participation from parents, child psychologists and teachers of grades 3 and 4. The questions were rephrased and reworded for 8-year-olds by consulting teachers of grades 3 and 4 and writers of children's manuals. In addition, grammar and language difficulty were further assessed.

The CPQ8-10 consists of 25 items organized into four health domains: oral symptoms (5 items), functional limitations (5 items), emotional wellbeing (5 items) and social wellbeing (10 items). The questions ask about the frequency of events in the last four weeks in relation to the child's oral health condition. The response options are the same as for the CPQ11-14: 0 = never, 1 = once/twice, 2 = sometimes, 3 = often and 4 = every day/ almost every day. The instrument also contains items to provide global rating of the child's oral health, worded as follows: "When you think about your teeth or mouth, would you say that they are…" and "How much do your teeth or mouth bother you in your everyday life?" Four-point response formats are offered, respectively from 0 = very good to 3 = poor and from 0 = not at all to 3 = a lot.

The questionnaire was assessed for readability, comprehension and ease of administration in a convenience sample from the patient population. A qualitative interview was also conducted concerning each child's understanding of instructions, wording of items, recall period and response options. The think-aloud and observational monitoring retesting techniques were also applied.

Validity and reliability were evaluated on 68 and 33 children respectively. The associations between the scores and global ratings were determined in order to assess construct validity. Internal consistency reliability was tested by means of Cronbach's alpha. Test-retest reliability was tested via ICC calculated using a one-way analysis of variance random effects parallel model. Construct validity was also assessed by determining the association between the scores and global rating. In the paediatric group, the researchers also examined the correlation between the overall score and the number of decayed tooth surfaces, and the difference between children with and without caries. Since the distribution of the scores was symmetrical, the rank correlation and Mann-Whitney test were used.

The researchers found that there was a positive correlation between the CPQ8-10 score and overall wellbeing rating ($r = 0.45$). The level of impact was higher in the oro-facial than the paediatric dentistry group; mean scores were 19.1 and 18.4 respectively. The mean score was higher in caries-affected than caries-free children, with DMFT = 21.1 and 14.7 respectively. Internal consistency reliability of the subscales ranged from moderate to high (coefficients ranged from 0.63 for OS to 0.78 for emotional wellbeing). The overall Cronbach's alpha for the scale was 0.88 in the paediatric group and 0.92 in the orofacial group. The ICC for the paediatric and orofacial groups was 0.75 and 0.78 respectively.

The researchers conclude that the results suggest good validity, internal consistency, reliability and test-retest reliability for the CPQ8-10, but that the scale does not demonstrate discriminative validity (Jokovic et al, 2004). All hypotheses regarding the construct validity of the CPQ8-10 and the relationship between the CPQ8-10 scores and global ratings were confirmed. Positive correlation was observed between all subscales and both global ratings, except between the functional limitation and social wellbeing scores and oral health rating. The researchers conclude that the

study results provide evidence of the discriminative properties of the CPQ8-10 and that more studies need to be done involving clinical and general populations in different cultures and languages. In addition, the outcome of the CPQ8-10 should be used in longitudinal studies, to determine responsiveness and clinical difference in order to measure the intervention outcomes and minimal clinical differences.

Two studies were conducted to assess the validity and reliability of CPQ8-10 in the Brazilian Portuguese language, one in a clinical setting (Martins et al, 2009) and the other in the general population (Barbosa et al, 2009). The cross-cultural adaptation of the original version of CPQ8-10 (Jokovic et al, 2004) into Portuguese was used for both studies. Martins et al administered the questionnaire to 59 children and clinical examinations were also done by a single examiner. The internal consistency was assessed by Cronbach's alpha, ICC was used to assess reliability among 40 children and discriminant validity was determined by the Kruskal-Wallis test. Barbosa et al (2009) recruited 210 schoolchildren; pretesting and test-retest reliability were also examined with 80 and 50 children respectively. In addition, the children were examined for dental caries, gingivitis, fluorosis and malocclusion. The researchers found that the Brazilian version of CPQ8-10 demonstrated good psychometric properties, including internal reliability, validity and ICC.

A study was conducted on a South Australia School Dental Services population; 374 of 842 children completed CPQ8-10 questionnaires to assess global ratings of oral health and overall wellbeing. Scores for all domains were calculated and clinical data were also measured, including dental caries and occlusion. CPQ8-10 was found to have an acceptable internal consistency and construct validity. Discriminant validity was also confirmed, since children with more caries and less acceptable occlusion reported poorer OHRQoL. These results suggest that the CPQ8-10 has the ability to measure OHRQoL in general populations (Do and Spencer, 2008). More recently, a study was conducted in 123 class four children, using CPQ8-10 after translation to Danish and back-translation. The validity and reliability were measured and found acceptable (Cronbach's alpha = 0.82). These results indicate that the Danish version of CPQ8-10 offers a valid and reliable measure of OHRQoL in Danish-speaking children (Wogelius et al, 2009).

2.4.3. Child Oral Health Impact Profile

The COHIP consists of 34 items under five subscales: oral health, which concerns specific oral symptoms such as pain and spots on the teeth; functional wellbeing, covering daily activities such as speaking clearly and chewing effectively; social-emotional wellbeing, such as items relevant to peer interaction and mood status; school, which is related to interactions in the school environment; and self image, with items related to the child's positive feelings about itself.

The initial instrument consisted of 54 items which were developed by Jokovic et al (2002). The development of COHIP passed through several phases: (a) development of an initial pool of 54 items from literature and expert review, (b) initial face validity: from 54 to 42 items (15 item dropped and 3 added), (c) initial item impact, which raised the number of items from 42 to 51 (8 items dropped and 17 added), (d) second face validity by revision and development of positive items (2 items dropped), (e) second items impact (9 items dropped, leaving 40) and (f) factor analysis and final revision of the questionnaire (4 items dropped) in order to evaluate whether the COHIP questionnaire had independent conceptual domains or not (Broder et al, 2007).

A study recruited 523 children aged 8-15 years from paediatric, orthodontic and craniofacial clinics in the USA and Canada in order to assess reliability and convergent and discriminant validity of the COHIP version. The results showed that COHIP had excellent scale and test-retest reliability. Discriminant and convergent validity were also determined and supported by comparisons among the four groups of children (Broder and Wilson-Genderson, 2007). Another study was conducted in the Netherlands, where the Dutch version of COHIP was administered to a sample of 510 children in Amsterdam. This version consisted of 38 items divided into five dimensions. The questions asked how often an event such as feeling unhappy because of teeth trouble had occurred over the past 3 months. Responses were on a five-point scale (1 = never to 5 = constantly), with the additional response option of "I don't know". Reliability was investigated by item correlation and Cronbach's alpha, then six items were excluded. Next, the questionnaire was examined using confirmative factor analysis, which showed that the model fitted less than an acceptable level (Geels et al, 2008).

2.4.4. The Child Oral Impacts on Daily Performance Index

The Child-OIDP questionnaire was validated among 11-12 year-olds in Thailand (Gherunpong et al, 2004). This instrument was derived from the OIDP with rephrasing and verbal modification to address children's intellectual, cognitive and linguistic ability. It is based on a modified version of the WHO's International Classification of Impairments, Disabilities and Handicaps (Locker, 1988). The Child-OIDP index was developed on a large number of population samples, which were used for dental health service planning. Theoretically, it is the same as the original OIDP and measures only oral impacts on daily performance at the level of the child (Gherunpong et al, 2004; Zamros and Nasruddin 2012).

The development and evaluation of the Child-OIDP index consisted of two steps, a pilot and a main study. The sample comprised children aged 11-12, attending class 6 in U-thong district, Suphan-buri province, Thailand. In the main study, the sample was children aged 11-12 years, in grade six, in the municipal area. The total number of children included in the study was 1,126. The Thai version of the OIDP index (Adulyanon and Sheiham, 1997) was used in its original form. Validity was examined on individuals and panels of children by observation and repeat interviews. The validity of the wording modifications was also tested by back-translation, whereby any language or wording changes were retranslated into English and validity was verified by experts in the use of the OIDP index in both languages, in order to ensure the conceptual and functional equivalence of the index. Content validity was assessed by a panel of experts in children's oral health-related quality of life. Three measures were used for the analysis of internal reliability: inter-item correlation, corrected item-total correlation and Cronbach's alpha. The analysis of test-retest reliability used weighted kappa statistics throughout the whole process of validation. During the development process, the OIDP index was modified and its psychometric properties were evaluated.

There was no negative correlation between any two items and the corrected item-total correlation coefficients were between 0.4 and 0.7, while the standard Cronbach's alpha coefficient was 0.82. The index showed very significant associations with perceived oral treatment need ($p < 0.001$) and perceived oral health

problems ($p < 0.001$). The validity and reliability of the index were confirmed by similar results in a re-evaluation study. The researchers conclude that the Child-OIDP index is a valid, reliable and practical measure of OHRQoL in 12-year-old Thai children (Gherunpong et al, 2004).

A French version of the Child-OIDP was also validated after translation and cultural adaptation. It was tested on 414 children aged 10 years in France. The children were also examined clinically and asked to rate their global oral health. The study found that Child-OIDP had acceptable psychometric properties and was suitable for use among children in France (Tubert-Jeannin et al, 2005). Another study was conducted to evaluate the psychometric properties of the Child-OIDP questionnaire with clinical examination among UK schoolchildren in Westminster. Analysis of the results showed that weighted kappa was 0.82, Cronbach's alpha coefficient was 0.58 and there was significant association with oral health needs and status ($p < 0.001$). These results confirm that the Child-OIDP is valid and reliable to be used in the UK on children aged 10-11 years (Yusuf et al, 2006). Two studies were conducted in South America, in Peru (Bernabe et al, 2007) and in Brazil (Al Castro et al, 2008), after cross-cultural adaptation into Spanish and Portuguese respectively. Both studies support the psychometric properties of Child-OIDP and show that it can be used to measure OHRQoL in Peruvian and Brazilian children.

2.4.5. The Early Childhood Oral Health Impact Scale

Preschool children can experience multiple oral health problems such as early childhood caries, eruption disruption and dental trauma (Li et al, 2008). Children in this age group (younger than 6 years) cannot be expected to give information on what has happened in their everyday life more than 24 hours ago (Rebok et al, 2001). Their parents or guardians, who have responsibility for their health, may have to be absent from work and spend money and time to attend to their dental care and treatment (Gift et al, 1995). For all these reasons, Pahel et al (2007) developed the ECOHIS in order to measure the OHRQoL for this age group. ECOHIS was developed and tested in the USA according to the criteria and guidelines introduced by Juniper et al (1996), Guyatt et al (1993) and DeVellis (2003). The development

process consisted of item generation and reduction. Subsequent testing of the instrument included pretesting, validity and reliability tests.

In summary, ECOHIS was developed in the USA for use with children aged between 3 and 5 years and their parents. It consists of two main parts: a child impact section and a family impact section, comprising four and nine items respectively. The child section has four sub-domains – child symptoms, child function, child psychology and self-image and social interaction – and the family section has two sub-domains: parental distress and family function. Responses are on a 5-point scale (0 = never to 5 = don't know). ECOHIS scores are obtained by summing responses for all 13 questions. The total score ranges between 0 and 52, with a higher ECOHIS meaning a poorer OHRQoL.

In the original ECOHIS study (Pahel et al, 2007), the 13 items was administered to 295 parents of 5-year-old children to assess construct validity and internal reliability. Test-retest reliability was assessed with another sample of 46 parents using ICC. The results confirmed the validity and internal consistency: Cronbach's alpha for the child and family sections was 0.91 and 0.95 respectively, while the ICC was 0.84. Li et al (2008) also assessed a French language version of ECOHIS in Canada after translation and back-translation of the original English version. They assessed internal consistency, test-retest reliability, convergent validity and discriminant validity, concluding that the French version was valid, with Cronbach's alpha of 0.79-0.82 and ICC of 0.95. Mean scores of the ECOHIS were 10.8, 3.4 and 2.7 for parents rating the child's oral health as "relatively good", "good" and "very good" respectively, while the mean scores for the community-based and clinical samples were 3.7 and 4.9 respectively. Another study was conducted in Hong Kong to assess the psychometric properties of a Chinese version of ECOHIS (Lee et al, 2009), which was again developed by forward and backward translation of the original version. A convenience sample of preschool children (n = 111) and their parents was recruited. Validity was assessed by the relationship between scores on the Chinese ECOHIS and caries level, while internal and test-retest reliability were also determined. Cronbach's alpha for the total ECOHIS was 0.91 and ICC was 0.64, indicating that this version of the ECOHIS was valid and reliable.

2.4.6. Summary of the Child Oral Health-related Quality of Life

It is important that researchers demonstrate that the measures of oral health related quality of life that have been developed are reliable and valid. There are a number of techniques for determining the internal consistency, reliability and validity of questionnaires and researchers have used different approaches for the measures of child oral health related quality of life that have been developed to date. Table 2.1 below summarises the psychometric information from published studies of cross-cultural validation of measures of child OHRQoL, a summary of each research paper is not provided for the sake of brevity.

A thorough analysis of the individual details of the reliability and validity of each translation would occupy a great deal of space, but in summary, Table 2.1 suggests that across a range of measures researchers have taken steps to ensure that measures are reliable and valid in their translated form. However reliability and validity are not the same as cross cultural equivalence - determining cross cultural equivalence requires a different process as outlined previously. From Table 2.3 (Page 53) we can see that for child measures of OHRQoL, most validations did not include the use of qualitative methods to determine the subjective equivalence of the scale. This brings into the question of whether the scales thus developed, while reliable, and having face validity and possible other forms of validity may not have exact cultural equivalence and therefore may only be of limited utility in cross cultural comparisons.

Table 2.1: Summary of published reports of cross-cultural validation of Child OHRQoL

Original Instrument	No. of items	Cross-cultural studies	Reliability		Validity		
			Internal consistency	Test-retest	Internal consistency	Test-retest	Internal consistency
Early Childhood Oral Health Impact Scale (ECOHIS) by Pahel et al, 2007	45	English version: Pahel et al, 2007	0.91	0.84	✓	x	✓
	45	French version: Li et al, 2008	0.82	0.95	✓	✓	✓
	45	Chinese version: Lee et al, 2009	0.91	0.64	✓	✓	x
	45	Spanish version: Talekar et al, 2005	0.81	x	✓	✓	✓
	45	Brazilian version: Tesch et al, 2008	0.98	0.74	✓	✓	✓
	45	Farsi version: Jabarifar et al, 2010	0.93	082	✓	✓	x
	45	Dutch version: Geels et al, 2008	0.84	✓	✓	✓	x
	45	Turkish version: Pekar P etl, 2011	0.93	0.86	✓	✓	✓
	45	Kiswahili and Luganda versions: Masumo et al, 2012	0.84	0.70	✓	✓	✓
Child Oral Health Impact Profile (COHIP) by Broder and Wilson-Genderson, 2007	34	English version: Broder and Wilson-Genderson, 2007	0.91	0.84	✓	✓	x
	38	Dutch version: Geels et al, 2008	0.84	x	Assessed by confirmative factor analysis		
	32	Dutch version: Geels et al, 2008	0.87	x	Assessed by confirmative factor analysis		
Child Oral Health Impact Profile (Child-OIDP) by Gherunpong et al (2004)	8	Thai version: Gherunpong et al (2004)	0.82	x	✓	x	✓
	8	Italian version: Bianco et al, 2010	0.57	0.70	✓	x	✓
	8	Arabic version: Nazik et al, 2010	0.73	x	✓	x	x
	8	Spanish version: Cortes Martinicorena et al, 2010	0.68	0.98	✓	✓	✓
	8	Spanish (Peru) version: Bernabe et al, 2007	0.63	0.85	✓	x	✓
	8	Portuguese (Brazil) version: Castro et al, 2008	0.63	0.79	✓	x	✓
	8	Kiswahili (Tanzania) version: Mtaya et al (2007)	0.77	0.80	✓	x	✓
	8	English version: Yosef et al, 2006	0.58	0.88	✓	✓	✓
	8	French version: Tubert-Jeannin et al, 2005	0.57	0.81	✓	✓	✓

Table 2.1 continued

Original Instrument	No. of items	Cross-cultural studies	Reliability		Validity		
			Internal consistency	Test-retest	Internal consistency	Test-retest	Internal consistency
Child Perceptions Questionnaire (CPQ8-10) by Jokovic et al, (2004)	25	English version: Jokovic et al, (2004)	0.89	0.75	✓	✓	✓
	25	Spanish (Mexican) version: Del Carmen and Iringoyen-Camacho, 2011	0.89	0.67	✓	✓	x
	25	Persian version: Jabarifar et al, 2011	0.86	0.82	✓	✓	✓
	25	Brazilian Portuguese version: Barbosa et al, 2009	0.95	0.96	✓	✓	✓
	25	Brazilian version: Martin et al, 2009	0.92	0.96	✓	✓	✓
	25	Danish version: Wogelius et al, 2009	0.82	x	✓	✓	x
	25	English version: Do and Spencer, 2008	0.82	x	✓	✓	x
	25	Brazilian Portuguese: Barbosa et al, 2011	0.93	0.74	✓	✓	x
	25	Brazilian version: Fernanda et al, 2013	x	0.93	✓	x	x
	25	Brazilian version: Ramos-Jorge et al, 2012	0.91	0.90	✓	x	x
	25	Bosnia and Herzogovina version: Hadzipasic-Nazdrajic, 2012	x	x	✓	x	✓
Child Perceptions Questionnaire (CPQ11-14) by Jokovic et al, (2002)	37	English version: Jokovic et al, (2002)	0.91	0.90	✓	✓	✓
	37	Persian version: Jabarifar et al, 2011	0.92	0.82	✓	✓	✓
	37	Thai version: Gururatana et al, 2011	0.90	0.60	✓	✓	x
	37	German version: Bakes et al, 2011	087	0.83	✓	✓	x
	37	Brazilian Portuguese version: Barbosa et al, 2009	0.95	0.92	✓	✓	✓
	36	Chinese version: McGrath et al, 2008, 2009	0.89	0.88	✓	✓	✓
	37	Danish version: Wogelius et al, 2009	0.87	x	✓	✓	x
	37	Brazilian Portuguese version: Goursand et al, 2008	0.86	0.85	✓	✓	x
	36	Arabic version: Brown and Al-Khayal, 2006	0.81	0.65	✓	✓	✓
	37	Brazilian Portuguese: Barbosa et al, 2011	0.94	0.74	✓	✓	x
	37	Brazilian version: Ramos-Jorge et al, 2012	0.72	0.88	✓	x	x
	37	English version: Do and Spencer, 2008	0.83	x	✓	✓	x

Table 2.1 continued

Original Instrument	No. of items	Cross-cultural studies	Reliability		Validity		
			Internal consistency	Test-retest	Internal consistency	Test-retest	Internal consistency
Short form version of the Child Perceptions Questionnaire Short form of (CPQ11-14) by Jokovic et al, (2006)	8 & 16	English version: Jokovic et al, (2006)	0.72- 0.83	0.71 – 0.77	✓	✓	x
	8 & 16	Thai version: Gururatana et al, 2011	0.50- 0.70	0.50-0.60	✓	✓	x
	8 & 16	Brazilian version: Torres et al, 2009	0.70 -0.84	0.98-0.97	✓	✓	✓
P-CPQ (6-14): Jokovic et al, (2003)	31	English version: Jokovic et al, (2003)	0.94	0.85	✓	✓	✓
	31	Brazilian version: Goursand et al, 2009	0.84	0.83	✓	✓	✓
	31	English version: Do and Spencer, 2008	0.81	x	✓	✓	x
	31	Chinese version: McGrath et al, 2008	0.82	0.83	✓	✓	✓
	31	Brazilian version: Barbosa etal, 2012	0.92	0.95	✓	x	x
	31	Brazilian version: Antunes et al, 2012	0.87	0.90	✓	x	x

2.5. Parental Perceptions of Child Oral Health-related Quality of Life

A debate continues regarding the measurement of health-related quality of life in children, as to whether it should be based on reports by parents or by children themselves (Le Coq et al, 2000). Most measurements of child HRQoL have been based on parental reports (Canning et al, 1992). More recently, appropriate questionnaire techniques have been developed to obtain valid and reliable information from the children concerned, although the information obtained from caregivers or parents remains very valuable (Jokovic et al, 2003).

Accordingly, Jokovic and co-workers (2003) decided to develop a parental/caregiver Perceptions Questionnaire (P-CPQ) when they constructed their Child Oral Health Quality of Life Questionnaire. The development of the P-CPQ followed the same procedures as those used by Guyatt et al (1986) and Juniper et al (1996). The P-CPQ asked about events in the last three months. The response options ranged from 0 = never to 4 = every day or almost every day; "don't know" responses were also allowed. Global ratings of the child's oral health and impact of the oral/orofacial condition on his or her overall wellbeing were also obtained, using a five-point response format from "excellent" to "poor" for oral health and from "poor" to "very much" for wellbeing (Jokovic et al, 2003).

The items of the P-CPQ were developed from the existing child health questionnaires and interviews with parents/caregivers of children with some dental disorders. The resulting 47 items were used in a study of 208 parents who provided data on their frequency and importance. The validity and reliability were assessed by another sample of 231 parents, of whom 79 completed two copies in order to assess test-retest reliability. The researchers found that P-CPQ had good construct validity and the discriminant validity among the three clinical groups was in the expected direction. They also found that the P-CPQ had excellent internal consistency reliability, with Cronbach's alpha of 0.94 and perfect test-retest reliability (ICC = 0.85) (Jokovic et al, 2003).

A study was conducted in the South Australia School Dental Services Population in order to assess and evaluate the CPQ and P-CPQ questionnaires. From a population of 1,401 children and their parents, 842 parents completed the questionnaire. It was found that the PPQ had suitable internal consistency with acceptable construct validity between global ratings of oral health and overall wellbeing. Discriminant validity was also confirmed in that parents with children who had more caries or less acceptable occlusion reported poorer OHRQoL (Do and Spencer, 2008). Another two studies were conducted in China (McGrath et al, 2008) and Brazil (Goursand et al, 2009) to evaluate and assess the psychometric properties of the Chinese and Portuguese versions of the P-CPQ questionnaire after cross-cultural adaptation into the two languages. The respective researchers found that both versions had acceptable psychometric properties, including internal consistency, test-retest reliability, construct validity and discriminant validity. These results confirmed that the Chinese and Brazilian versions of the P-CPQ were reliable and valid for use in assessing parental perceptions of the impact on the child's quality of life of his or her oral health status. Future studies are needed on versions in other languages and longitudinal studies would also be valuable.

Additionally, a study was conducted in New Zealand using data from a consecutive clinical sample of the parents/caregivers of children receiving treatment under general anaesthetic using the P-CPQ. An initial questionnaire was completed before or during treatment and the follow-up questionnaire was completed after 1 to 4

weeks. The results showed that the CPQ11-14 was an acceptable evaluative measure to differentiate the impact on OHRQoL before and after treatment (Malden et al, 2008).

In conclusion, child OHRQoL instruments have been developed for children over eight years old, whereas proxy reporting by parents and carers has generally been adopted for younger children. However the importance of obtaining children's self reports about their health, emotional, social and physical status is increasingly recognized in child health research (Cremeens et al, 2006).

The level of agreement between children's own reports and parents' reports of their child's health is relatively unclear. Levels of agreement are reported as poor to high and according to Eiser and Morse (2001) are vary according to the oral health related quality of life domain. For example agreement is higher for physical aspects compared with social or emotional aspects. Eiser and Morse also report that agreement is higher between parents and chronically sick children compared with parents and healthy children. Agreement may also be affected by the age of the child, for example, scores in the emotional domain for children aged 10-11 years old agreed less with their parents than children 8-9 years old (Jokovic et al, 2003). Furthermore parent's functioning and well-being also affects their perception of their child's well being (Jokovic et al, 2003).

While parents may report biased information about the OHRQoL of their children, they still provide useful information. The proxy report cannot represent the full experience of the child but it will enhance the information provided to the clinician and provides a point of triangulation (Barbosa and Gavião, 2008).

2.6. Cross-cultural Adaptation of Health-Related Quality of Life Measures

2.6.1. Introduction

As multicultural and multinational research projects have multiplied, the adaptation of health measurements to be used in other languages has also increased rapidly. Cross-cultural adaptation has been used for several years in the social field, in epidemiological and behavioural studies, and more recently in health sciences, especially with the growing research into health-related quality of life. In order to make worthwhile comparisons between countries in terms of population, services, quality, costs and outcomes of health services, researchers need an internationally agreed system to assess the validity and reliability of their instruments (Knudsen et al, 2000).

Several studies have examined the health services of different countries and some authors have generalised findings to other populations (Abe and Wiseman, 1993). There is research evidence that the nature of society and culture in Western countries differs from those of Asian countries, in terms of language, lifestyle and education. In addition, countries can differ according to public strategy, attitudes and socioeconomic conditions (Berry and Sabatier, 2010), so it is important to translate questionnaires using cross-cultural adaptation in order to maintain the meaning and intention of the original items (Sperber, 2004). Empirical evidence shows that culture can influence a person's activities, thinking and behaviour. Accordingly, when researchers wish to assess health status and perceptions of quality of life and to compare results with those in the original setting, they need to ensure that the instrument used is culturally adapted (Hanh et al, 2005).

Thus, if researchers have no appropriate HRQoL measure in their own language, they have two options: to develop a new measure or to modify one previously validated in another language, which is known as cross-cultural adaptation (Guillemin et al, 1993).

2.6.2. Strategies in cross-cultural adaptation

A direct translation strategy is inadequate because it keeps the disadvantages of the original questionnaire and does not permit modifications which reflect differences in culture and values. Furthermore, direct translation of a questionnaire does not assure that it is as valid as the original questionnaire, as it may include items which are misunderstood by the new population (Guyatt, 1993). Culture is an important factor, in the form of a variation of expression between populations, so the instruments

should go through a cultural adaptation process before being used in a different country. Even when translation is done with great care, cultural factors may not be accurately conveyed (Maneesriwongul and Dixon, 2004).

In the present context, assessing the psychosocial impairment of children in areas such as family, school, friends and community can be affected by social and cultural factors. Descriptive items which assess symptoms are easier to translate than cultural items (Canino and Bravo, 1999

Cross-cultural adaptation could be considered in five different situations, listed in Table 2.2, the first being where the questionnaire is to be used in the same population with the same culture and language in which it was developed, in which case no translation or adaptation is needed. The second situation is where it is to be used in the same country with the same language but with a different culture, such as among immigrants; in this case, cultural adaptation is required but there is no need for translation. The third situation is where the questionnaire is to be used in another country with the same language, in which case there is no need for translation, but cultural adaptation is required. The fourth scenario is where the questionnaire is used in the same country but with new immigrants, when translation and cultural adaptation will both be needed. Finally, if the questionnaire is to be used in another country with a different culture and language, again both translation and cultural adaptation will be necessary (Guillemin, 1993).

Table 2.2: The five different settings for cross-cultural adaptation of OHRQoL after Guillemin 1993

Target population	Situation	Recommended process
1. Same population	In the same language, country and country	Use the same questionnaire
2. Established immigrants	In different culture but same language and country	Need cultural adaptation
3. Another country but with the same language	Same language but different culture and country	Need cultural adaptation
4. New immigrant	Same country but different culture and language	Need translation and cultural adaptation
5. Different population	Different culture, language and country	Need translation and cultural adaptation

According to Guillemin et al (1993), the guidelines for obtaining an effective and practical cross-cultural adaptation of HRQoL instruments include semantic, idiomatic, experiential and conceptual equivalence in translation. Flaherty et al (1988) recommend that obtaining a valid cross-cultural adaptation of any instrument requires consideration of several criteria: content, semantics, technical and conceptual issues. This can be done using translation, back-translation, committee review, pretesting and weighting scores. Acquadro et al (2008) review the literature on the common methods used to translate HRQoL questionnaires for use in populations different from the original ones. They searched in MEDLINE, Embase and the Mapi Research Trust's database and found that forty-five articles met the inclusion criteria, while twenty-three articles represented seventeen guidelines. They recommend that in order to adapt questionnaires, researchers should follow a multi-step method.

2.6.3. Guidelines for cross-cultural adaptation of OHRQoL questionnaires

This review will focus on the guidelines proposed by Guillemin and Beaton, because they were the first, in 1993, to propose an extensive review of cross-cultural adaptation, which was followed by a research study in 2000. This is also the method currently used by the American Association of Orthopaedic Surgeons (Beaton and Guillemin, 2000; Acquadro et al, 2008).

2.6.3.1.Forward translation

The first stage in adaptation is forward translation from the original language to the target language by at least two independent bilingual translators whose mother tongue should be the target language and who should have different profiles and backgrounds. For example, one of the translators should be informed of the concepts being covered by the questionnaire and should have a medical background, while the other should be less influenced by academic goals. Each should write a report of the translation that he or she has completed, summarising all the difficulties encountered, choices made and uncertainties remaining (Beaton et al, 2000).

Waters et al (2006) agree that translators of QoL instruments should be native speakers of the target language, adding that they should be familiar with both of the cultures concerned. In addition, they should follow certain guidelines, such as focusing on conceptual equivalence rather than word-for-word translation. Translators should also try to be simple, clear and concise, taking into account the

age of the target group to avoid any terms which might be difficult to understand. For example, a person who studies or works with young children would be a reasonable choice in the case of translating a questionnaire for children, as he or she would have the experience needed to choose words and phrases which suited the age group.

2.6.3.2. Synthesis of translations

All translators and a recording observer should next meet to synthesise the resulting translations. Working from the original questionnaire with translated versions, a synthesis of the translations is first conducted to produce one common translated version. This can be achieved by the addition to the team of an unbiased person whose role is to work as a mediator during discussions of differences in translated versions and to provide documentation of the process (Acquadro et al, 2008), in the form of a written report addressing all problems and how they were resolved. It is important that agreement is reached, rather one than one person compromising to resolve such issues (Beaton et al, 2000).

2.6.3.3. Back-translation

A back-translation should next be made by a translator whose mother tongue is the original language of the questionnaire. It is also helpful if the back-translator is familiar with the culture in which the questionnaire originated and has knowledge of its subject (Van Widenfelt et al, 2005). Conversely, Guillemin et al. (1993) argue that in order to avoid bias, the back-translator should preferably not understand the subject of the questionnaire. Working from the translated version of the questionnaire and totally blind to the original version, this translator should simply translate the questionnaire back to the original language. This stage is a process of validity checking to make sure that the translated version contains items equivalent to those in the original version. This step will also tend to reveal unclear wording in the translations. At least two back-translations should be made and a written report produced, to indicate whether the back-translation reflects accurately the content, meaning, instructions and response categories of the original version (Acquadro et al, 2008). However, back-translation is a check on only one type of validity and it is better to highlight gross inconsistencies and conceptual errors in the initial translation process (Beaton et al, 2000).

2.6.3.4. Committee review

The composition of the review committee is very important to the achievement of cross-cultural equivalence. It should be composed of methodologists, health professionals, language professionals and all the forward and back-translators. The original developers of the questionnaire should be in close contact with the committee, whose role is to review all translated versions and reach agreement on any inconsistency (Beaton et al, 2000).

This expert committee makes critical decisions; therefore a written report should be made of the issues discussed and the proposals or decisions made about them. Decisions will need to be taken by the committee in order to achieve equivalence between the source and target versions in four areas (Guillemin et al,1993). *Semantic* equivalence means that the words give the same meaning to a given item; it also covers any grammatical difficulties in the translation. *Idiomatic* equivalence refers to where the committee may have to formulate an equivalent expression in the new version. *Experiential* equivalence means that the questionnaire item should be replaced by a similar item that is in fact experienced in the target culture. *Conceptual* equivalence means that the concept explored should be valid in the target culture. The committee should examine the source and (back-) translated questionnaires for all these equivalences. Items, instructions and response options must be measured.

2.6.3.5. Pre-test

The pretest stage is needed to verify equivalence in the source and final versions. Ideally, 30-40 samples will be tested. Each subject should complete the questionnaire and be interviewed about the meaning of each item. Distribution of responses should be examined to check the proportion of any missing item. This stage provides an evaluation of content validity; however it does not deal with construct validity, reliability or item response patterns, which are critical aspects of the quality of cross-cultural adaptation (Beaton et al, 2000). Guillemin et al (1993) state that in the case of immigrant interviewees, there are two additional considerations: choosing the language and a dual-format measure for immigrants.

2.6.3.6. Coordinating committee for appraisal of the adaptation process

The final stage in the adaptation process is the submission of all reports and forms to the developer of the instrument or the committee keeping track of the translated version, to ensure that all steps have been performed and fully documented.

2.6.4. Review Cross-cultural adaptation of frequently used measures of OHRQoL in adult and children

Cross-cultural adaptation is increasingly important in order to understand human behaviour, health and psychological processes. Adaptation refers to assessing a similar item in a different culture. Guillemin et al (1993) and Acquadro et al (2008) recommend the following: care should be taken during cross-cultural adaptation to incorporate a team of varied experts, there should be regular contact with the original authors to minimise major errors and a pilot study should be conducted for new items before they are submitted to a larger group. The authors note that cross-cultural adaptation should enable the same HRQoL instrument to work well in different cultural contexts, giving the opportunity to make comparisons in HRQoL between different national and cultural groups, and that it is less costly and time consuming than generating new instruments.

A well validated OHRQoL instrument is considered to have the ability to assess the patient's self-reported perceptions. The scientific literature contains a consensus that for an instrument to be valid, reliable and responsive, it should include at least an assessment of physical, functional and mental status and social interaction. According to Guillemin et al (1993) and Herdman et al (1998), the cross-cultural adaptation should achieve semantic, idiomatic, experiential and conceptual equivalence by the translation, back translation, committee review, qualitative interview and pretesting methods.

Table 2.3 shows the most common cross-cultural adaptations of adult OHRQoL measures. Five tools – OHIP-49, OHIP-14, OIDP, GOHAI and OH-QoL-UK – were assessed through a validation process and translated into other languages, a summary of each research paper is not provided for the sake of brevity.

All 43 cross-cultural adaptation studies used forward and back translation, 90% (39 studies) used committee review, 35 (70%) used a pretesting stage and only 5 (10%) included a qualitative interview phase. Of the adult OHRQoL studies reviewed, only

five met the guidelines and recommendations by Guillemin et al (1993) and by Beaton and Guillemin (2000). Four of these studies were of the OIDP instrument, with versions in Korean (Jung et al, 2008), Swedish (Ostberg et al, 2008), Kiswahili (Kida et al, 2006) and Greek version (Tsakos et al, 2001). The fifth study was a translation of the GOHAI into Malay (Othman et al, 2006).

Table 2.3: Cross-cultural adaptation of frequently used instruments to measure Adult OHRQoL

Original Instrument / No. Of items	No. of items	Cross-cultural studies	Cross-cultural validation studies				
			Forward translation	Back translation	Committee review	Qualitative interviews	Pre-testing
Oral Health Impact Profile(OHIP- 49) by Slade and Spencer (1994) / 49	49	Swedish version: Larsson et al, 2004	Yes	Yes	Yes	No	No
	49	Chinese version: Wong et al, 2002	Yes	Yes	No	Yes	Yes
	49	Arabic version: Al-Jundi et al, 2007	Yes	Yes	Yes	No	Yes
	49	Japanese version: Yamazaki et al, 2007	Yes	Yes	Yes	No	Yes
	49	Dutch version: Van der Meulen et al, 2007	Yes	Yes	Yes	No	No
	49	Korean version: Bae et al, 2007	Yes	Yes	Yes	No	Yes
	49	Spanish version: Lopez and Baelum, 2006	Yes	Yes	Yes	No	Yes
	49	Hungarian version: Szentpetery et al, 2006	Yes	Yes	Yes	No	Yes
	49	German version: John et al, 2006	Yes	Yes	No	No	Yes
Oral Health Impact Profile (OHIP- 14) Slade 1997 / 14	14	Greek version: Roumani et al, 2010	Yes	Yes	Yes	No	No
	14	Persian Version: Navabi et al, 2010	Yes	Yes	Yes	No	No
	14	Spanish version: Montero-Martin et al, 2009	Yes	Yes	Yes	No	Yes
	14	Serbian version: Stančić I, et al, 2009	Yes	Yes	Yes	No	Yes
	14	Croatian and Slovenian version: Rener-Star et al, 2008	Yes	Yes	Yes	No	Yes
	14	Korean version: Bae et al, 2007	Yes	Yes	Yes	No	Yes
	14	German version: John et al, 2006	Yes	Yes	Yes	No	Yes
	14	Turkish version: Mumcu et al, 2006	Yes	Yes	Yes	No	Yes
	14	Chinese version: Xin and Ling, 2006	Yes	Yes	No	No	Yes
	14	Brazilian version: Oliveira and Nadnvsky, 2005	Yes	Yes	Yes	No	Yes
	14	Malaysian version: Saub et al, 2007.	Yes	Yes	No	Yes	No
	14	Hebrew version: Kushnir et al, 2004	Yes	Yes	No	No	No
	14	Swedish version: Larsson et al, 2004	Yes	Yes	Yes	No	No
	14	Japanese version: Ikebe et al, 2004	Yes	Yes	Yes	No	Yes
	14	Sinhalese version: Ekanayake and Perera, 2003	Yes	Yes	No	No	Yes
	14	Finnish version: Harju et al, 2002	Yes	Yes	No	No	No

Table 2.3 continued

Original Instrument/ No. Of items	No. of items	Cross-cultural studies	Cross-cultural validation studies				
			Forward translation	Back translation	Committee review	Qualitative interviews	Pre-testing
Oral Impacts on Daily Performance (OIDP) by Adulyanon and Sheiham, (1997) / 9	9	Albanian version: Thelen et al, 2011	Yes	Yes	Yes	No	Yes
	9	Korean version: Jung et al, 2008	Yes	Yes	Yes	Yes	Yes
	9	Greek version: Tsakos et al, 2001	Yes	Yes	Yes	Yes	Yes
	9	Swedish version: Ostberg et al, 2008	Yes	Yes	Yes	Yes	Yes
	9	Persian version: Dorri et al, 2007	Yes	Yes	No	No	Yes
	9	Japanese version: Naito et al, 2007	Yes	Yes	Yes	No	Yes
	9	Kiswahili (Tanzanian) version: Kida etal, 2006	Yes	Yes	Yes	Yes	Yes
	9	Norwegian Version: Astrom et al, 2005	Yes	Yes	No	No	Yes
Geriatric (General) Oral Health Assessment Index (GOHAI) by Atchison and Dolan (1990) / 12	12	Spanish version: Sánchez-García et al, 2010	Yes	Yes	Yes	No	No
	12	Romanian version: Murariu et al, 2010	Yes	Yes	Yes	No	No
	12	Arabic version: Atieh, 2008.	Yes	Yes	Yes	No	Yes
	12	Arabic version: Daradkeh et al, 2008	Yes	Yes	Yes	No	Yes
	12	German version: Hassel et al, 2008	Yes	Yes	Yes	No	No
	12	Turkish version: Ergül and Akar, 2008.	Yes	Yes	Yes	No	No
	12	Malay version: Othman et al, 2006.	Yes	Yes	Yes	Yes	Yes
	12	Japanese version: Naito et al, 2006	Yes	Yes	Yes	No	Yes
	12	Swedish version: Hägglin et al, 2005	Yes	Yes	Yes	No	No
	12	French version: Tubert-Jeannin et al, 2003	Yes	Yes	Yes	No	No
	12	Chinese version: Wong et al, 2002	Yes	Yes	Yes	No	No
UK oral health related quality of life measure (OH-QoL-UK) by McGrath and Bedi (2003) / 16	16	Arabic version: McGrath et al, 2003	Yes	Yes	Yes	No	Yes
	16	Brazilian version: Dini et al, 2003	Yes	Yes	Yes	No	No

Table 2.4 shows the most common cross-cultural adaptations of child OHRQoL measures. The table lists studies that have undertaken a cross-cultural validation of an existing measure of OHRQoL. The purpose of this table is to summarise whether in the methodology of each paper there is a clear description that authors undertaken steps matching the criteria of cross-cultural validation identified by Guillemin et al (1993) and by Beaton and Guillemin (2000). A summary of each research paper is not provided for the sake of brevity.

Six instruments were identified and assessed through a validation process for translation into other languages: ECOHIS (Pahel et al, 2007), COHIP (Broder and Wilson-Genderson, 2007), Child-OIDP (Gherunpong et al, 2004), CPQ8-10 (Jokovic et al, 2004), CPQ11-14 (Jokovic et al, 2003) and the short form of CPQ11-14 (Jokovic et al, 2006). All 28 of the studies listed in Table 2.4 used forward and back-translation during cross-cultural adaptation, 22 (90%) used committee review, 24 (80%) used pretesting and only 10 (30%) used qualitative interviews. Overall, only seven of the studies met the validation requirements of cross-cultural adaptation by including all of forward and back-translation, committee review, qualitative interview and a pretest stage. These studies and the versions produced were ECOHIS: Brazilian (Tesch et al, 2008) and Farsi (Jabarifar et al, 2010); Child-OIDP: Italian (Bianco et al, 2010), Brazilian Portuguese (Castro et al, 2008), Kiswahili (Mtaya et al, 2007) and French (Tubert-Jeannin et al, 2005) and CPQ8-10: Mexican Spanish version (Del Carmen and Irigoyen, 2011).

The adaptation of an existing questionnaire to a different culture as described in this section requires careful attention and the collaboration of many people. It has several advantages: it provides a common measure for the investigation of OHRQoL within different cultures; it offers a standard measure for use in international studies; it allows comparisons between different groups on a standard measure; it allows to inclusion of immigrants, avoiding the frequent bias of representing only the dominant culture; and it is less costly and time-consuming than generating a new

In conclusion, this review of the cross cultural adaptation of measures of oral health related quality of life has demonstrated that in general very few studies met all the criteria suggested as necessary for a valid cross cultural adaptation of a

measure. Only five studies (covering two measures: the OIDP and the GOHAI) of measures of OHRQoL in adults met all the criteria for cross cultural validation, similarly for measures of OHRQoL in children only seven studies of cross validation (across four measures) met all the criteria. This suggests that the use of such measures may not yield valid comparisons across cultures and international settings since there is insufficient evidence of equivalence in the items that make up the scale.

Table 2.4: Cross-cultural adaptation of frequently used instruments to measure A child OHRQoL

Original Instrument / No. Of items	No. of items	Cross-cultural studies	Cross-cultural validation studies				
			Forward translation	Back translation	Committee review	Qualitative interviews	Pre-testing
Early Childhood Oral Health Impact Scale (ECOHIS) by Pahel et al, 2007 / 45	45	French version: Li et al, 2008	Yes	Yes	Yes	No	Yes
	45	Chinese version: Lee et al, 2009	Yes	Yes	No	No	Yes
	45	Spanish version: Talekar et al, 2005	Yes	Yes	Yes	No	Yes
	45	Brazilian version: Tesch et al, 2008	Yes	Yes	Yes	Yes	Yes
	45	Farsi version: Jabarifar et al, 2010	Yes	Yes	Yes	Yes	Yes
Child Oral Health Impact Profile (COHIP) by Broder and Wilson-Genderson, 2007 / 34	34	Dutch version: Geels et al, 2008	Yes	Yes	Yes	No	Yes
Child Oral Health Impact Profile (Child-OIDP) by Gherunpong et al (2004) / 8	8	Italian version: Bianco et al, 2010	Yes	Yes	Yes	Yes	Yes
	8	Arabic version: Nazik et al, 2010	Yes	Yes	Yes	No	No
	8	Spanish version: Cortes Martinicorena et al, 2010	Yes	Yes	Yes	No	Yes
	8	Spanish (Peru) version: Bernabe et al, 2007	Yes	Yes	Yes	No	Yes
	8	Portuguese (Brazil) version: Castro et al, 2008	Yes	Yes	Yes	Yes	Yes
	8	Kiswahili (Tanzania) version: Mtaya et al 2007	Yes	Yes	Yes	Yes	Yes
	8	French version: Tubert-Jeannin et al, 2005	Yes	Yes	Yes	Yes	Yes
Child Perceptions Questionnaire (CPQ8-10) by Jokovic et al, (2004) / 25	25	Spanish (Mexican) version: Del Carmen and Irigoyen-Camacho, 2011	Yes	Yes	Yes	Yes	Yes
	25	Persian version: Jabarifar et al, 2011	Yes	Yes	Yes	No	No
	25	Brazilian Portuguese version: Barbosa et al, 2009	Yes	Yes	Yes	No	Yes
	25	Danish version: Wogelius et al, 2008	Yes	Yes	Yes	No	Yes
Child Perceptions Questionnaire (CPQ11-14) by Jokovic et al, (2003) / 37	37	Thai version: Gururatana et al, 2011	Yes	Yes	No	Yes	No
	37	German version: Bakes et al, 2011	Yes	Yes	Yes	No	Yes
	37	Brazilian Portuguese version: Barbosa et al, 2009	Yes	Yes	Yes	No	Yes
	36	Chinese version: McGrath et al, 2008	Yes	Yes	Yes	No	Yes
	37	Danish version: Wogelius et al, 2008	Yes	Yes	Yes	No	Yes
	37	Brazilian Portuguese version: Goursand et al, 2008	Yes	Yes	Yes	No	Yes
	36	Arabic version: Brown and Al-Khayal, 2006	Yes	Yes	No	No	Yes
Short form version of the Child Perceptions Questionnaire Short form of (CPQ11-14) by Jokovic et al (2006) / 8& 16	8 & 16	Thai version: Gururatana et al, 2011	Yes	Yes	No	Yes	No
	8 & 16	Brazilian version: Torres et al, 2009	Yes	Yes	Yes	No	Yes

3. DEVELOPMENT OF AN ARABIC VERSION OF CPQ8-10 FOR USE IN SAUDI ARABIA (STUDY ONE)

3.1. Introduction

Most OHRQoL measurement tools, especially those for use with children, have been developed in America or Europe (Jokovic et al, 2002). A few OHRQoL questionnaires for children have been developed in languages other than English (Gherunpong, 2004), but to date no studies have been undertaken to assess the cross-cultural adaptation of the OHRQoL instrument for use in children aged 8-10 years in Arabic countries.

3.2. Aims and objectives of Study One

The aim of the first study was the cross-cultural adaptation of an instrument to measure COHRQoL. The objectives were:

- To adapt the COHRQoL instrument (CPQ8-10) devised in Canada by Jokovic et al (2004) for use in Saudi Arabia.
- To adapt the Parental Perceptions of Child Oral Health-related Quality of Life instrument (PPQ6-14) developed by Jokovic et al (2003), for use in Saudi Arabia.

3.3. Ethical approval, consent and permission

- Ethical approval for conducting the research was sought from the Directorate of Health Affairs in Alhasa (Appendices 1 and 2).
- Informed consent was obtained from each child's parent for the interview (Appendices 3 and 4), after they had read the patient information sheet (Appendices 5 and 6).
- Permission to use the COHRQoL instruments (CPQ8-10 and P-CPQ6-14) for cross-cultural adaptation was also obtained from the original author by email through my first supervisor, Professor Tim Newton.

3.4. Methods

A cross-sectional epidemiological survey was undertaken in three types of dental clinic in Alhasa, Saudi Arabia: general dental practitioner clinics at primary health care centres (PHCCs), a paediatric dental clinic at a Dental Centre (DC) and the Oral

and Maxillofacial Department at King Fahad Hospital Hofuf (KFHH). In order to facilitate cross-cultural adaptation of the COHRQoL instruments, 20 children aged 8 to 10 years who attended the clinics were recruited, as were their parents. The children who participated were free from any systematic and/or learning disabilities. Their parents also participated by completing the Parental Perception Questionnaire (P-CPQ6-14). The following subsections set out the process of cross-cultural adaptation, beginning with translation.

3.4.1. Translation

The aim of this stage was to produce an Arabic version of the questionnaires, using forward translation. It was undertaken by five qualified bilingual translators (two dentists, two English teachers and one general practitioner) working independently to translate the original English questionnaires into Arabic. The translators were chosen from different backgrounds in order to represent different perspectives. Before the translation process, the researcher briefly explained the aims of the questionnaires and described the target groups. The translators were also asked to note any word or items which were difficult to translate or understand. This allowed the detection of any errors and divergent interpretations of ambiguous items in the original. Following the forward translation, all the translators and the researcher held a panel discussion (Figure 3.1), resulting in the production of single Arabic versions of the parental questionnaire (Appendix 7) and of the child questionnaire (Appendix 8).

Figure 3.1: Discussion panel

3.4.2. Back-translation

The initial Arabic version was next back-translated into English, by a different team of five bilingual qualified translators (two dentists, one English teacher, one paediatric psychiatrist and one general practitioner). The original version was not given to them, to avoid bias in their back-translation. The same process as in the forward translation was then carried out to produce single back-translated English versions of the parent (Appendix 9) and the child (Appendix 10) questionnaires.

3.4.3. Committee review

The review committee comprised the researcher and four translators: two direct translators and two back-translators (Figure 3.2). They reviewed the translations in terms of comprehensive and semantic equivalence, to ensure that the Arabic versions were considered satisfactory by all of them.

Figure 3.2: The review committee

3.4.4. Qualitative interviews

The next step was to conduct semi-structured interviews with separate samples in the three different locations referred to above (PHCC, DC and KFHH) (Figure 3.3). The aim was to assess the conceptual and item equivalence between the source and target cultures with respect to oral health. In addition, this process sought to identify any other impacts or problems which were not covered in the questionnaires. The focus

of the interviews was on the ways in which participants' oral problems affected their daily life and psychosocial wellbeing. The Arabic translations of the questionnaires were then shown to each child and to their parents, who were asked to comment on the relevance of each item and whether the meaning of each statement was clear. Each interview was transcribed and checked for accuracy from the tape (Appendix 11). Words and phrases that described the domains of interest were identified and a code was inserted into the text. The data were then sorted according to these domains.

Figure 3.4: Qualitative interview

The CPQ 8-10 was applied in the form of an interview, with respondents being given the opportunity to comment in each question. Three children with their parents were selected randomly from three different clinics. The language with the interview was informal and the questionnaire referred to the past four weeks and ~~we~~ focused on the comprehensibility of the words. All questions were read to the children from the questionnaire form. The time was not measured as the aim of the interview was test the language understanding. Consent was obtained for the intereview from the parents and also the child who agreed verbally. Where children experienced problems understanding item. The interviewer discussed question with the child and their parent.

3.4.5. Second committee review

A second committee was then formed of the researcher and four translators: a dental specialist, a paediatric psychiatrist, a general practitioner and an English teacher. Its role was to consolidate all the versions of the questionnaires and to develop the pre-final versions of the questionnaire for the children (Appendix 8) and their parents (Appendix 7), for use at the pretest stage. The decisions made by this committee targeted four areas: semantic, idiomatic, experiential and conceptual equivalence.

3.4.6. Pretesting of the pre-final version

A convenience sample of 20 children with their parents was selected to complete the adapted questionnaire in order to check the clarity and comprehensibility of the wording. This stage was designed to check whether the target group interpreted the meaning of each item appropriately. After each person had completed the task, he/she was asked to comment on the questionnaire as a whole. Then some particular items were selected and participants were asked: “What do you think is meant by this question?” This was done to ensure that each final item was understood as having a meaning equivalent to that of the equivalent source item.

3.5. Findings from cross-cultural adaptation

3.5.1. Translation

The translations and back-translations were generally rated as easy and no items were considered impossible to translate. However, three items were considered difficult to translate, all of them relating to psychosocial issues. For example, the general practitioner from the forward translation team reported difficulty with questions 15 and 16, which referred respectively to the child having been “upset” and feeling “frustrated” in the last four weeks. One of the dentists on the forward translation team also had difficulty with question 19 in the parent questionnaire, which referred to being “anxious and fearful”. These difficulties were resolved during the first committee meeting, when the four translators and researcher shared their experiences regarding the translation. With these few exceptions, most of the items in the two original questionnaires were rated as easy to translate by all of the translators.

3.5.2. Committee review

All members of the first committee agreed that the final Arabic version was clear and easy to understand. However, the paediatric psychiatrist on the second committee commented that some items, such as questions 15 and 16 (which, as noted above, used the terms “upset” and “frustrated”), needed to be explained to child interviewees. These difficulties were resolved by supervising the children during the interview to clarify the meaning. The paediatric psychiatrist also suggested that the researcher should provide children with synonyms of “upset” and “frustrated”, such as “disappointed” and “annoyed” respectively.

3.5.3. Qualitative review

During the qualitative review, patients and their parents were shown the Arabic version of the questionnaire and asked to comment on the relevancy and their understanding of each question. In addition, parents were asked if any items were missing. Most of the items in the parents’ questionnaire were understood and applicable. However, some of those in the child questionnaire were ambiguous and needed to be explained to the children. These were items assessing the social functioning of the children, such as numbers 15, 16 and 17. One parent who was interviewed in the dental centre mentioned the difficulty that children had in understanding items referring to being frustrated and shies, suggesting that they should be clarified by the use of synonyms. Another parent, in the PHCC group, called for clarification of a question which referred to the child being upset because of his/her teeth, again by using a different word with the same meaning. These difficulties were resolved during interviews by providing supervision of the children and explanation of unclear items.

The children demonstrated understanding of the questions but two children commented on the length and wording of two questions. One eight year old child from the Primary Health Care Centre (PHCC) had difficulty understanding the words‘frustration’ and ‘embarrassment’. The solution was to explain the meaning of these items or provide a synonym, such as “uncomfortable” for “embarrassed” and “annoyance” for “frustration”. This improved the face validity of the questionnaire contents for the Saudi sample. The other child with his parent, in the PHCC group, asked for clarification of a question which referred to the child being “upset” because

of his teeth, again by using a different word with the same meaning e.g. sad or crying. Such difficulties were resolved during the interviews by providing supervision of the children and explanation of unclear items.

3.5.4. Pretesting

All parents who participated in the pretest stage agreed that the structure and instructions were easy and clear. However, some children, especially those aged 8 years, again found some questions difficult to understand, so they needed explanation from their parents or the researcher during the interview. These were items referring to frustration and embarrassment. Once more, the solution was to explain the meaning of these items or to provide a synonym, such as “uncomfortable” for “embarrassed”.

3.6. Findings from the pre-test questionnaires

3.6.1. Participants’ characteristics

Twenty children and their parents participated in the first study. Among the children there were ten boys and ten girls. As for the age of the children, 35% were 8 years old, 30% were 9 and 35% were 10. A quarter of the children took part in the dental centre (DC), a quarter in the King Fahad Hospital (KFHH) and half in Primary Health Care Centre PHCCs. Of those accompanying the children, 50% were mothers, 40% fathers and 10% others. This last group, all of whom were with children in the PHCC sample, were their older siblings (Table 3.1).

Table 3.1: Characteristics of the children and their parents in the first study

	DC*(%)	KFHH* (%)	PHCC* (%)	Total (%)
No. of cases	5 (25)	5 (25)	10 (50)	20
Gender of the child				
Male	1(5)	3 (15)	6 (30)	10 (50)
Female	4 (20)	2 (10)	4 (20)	10 (50)
Accompanied by				
Father	2 (10)	3 (15)	3 (15)	8 (40)
Mother	3 (15)	2 (10)	5 (25)	10 (50)
Other	0 (0)	0 (0)	2 (10)	2 (10)
Age of the child (years)				
8	2 (10)	1 (5)	4 (20)	7 (35)
9	1 (5)	1 (5)	4 (20)	6 (30)
10	2 (10)	3 (15)	2 (10)	7 (35)

* (DC) Dental Centre, (KFHH) King Fahad Hospital, (PHCC) Primary Health Care Centre

3.6.2. Findings from the parental perspective questionnaire

3.6.2.1. Descriptive data and subscale scores

There were 31 items in the parental questionnaire. For the total scale, the median, mean an SD scores of the respondents were 16.2, 19.3 and 6.1 respectively. There were 13 questions about oral symptom of the child, for which the median, mean and SD scores were 4.9, 4.6 and 1.6 respectively. There were 12 items about the Functional limitations on the child, with median, mean and SD scores of 5.4, 4.9 and 1.6 respectively. Emotional well-being 9 items with median, mean and SD scores of 5.9, 5.1 and 1.4 respectively. Finally, 14 items about the social wellbeing of the child, the respective figures were 5.6, 4.7 and 1.5 (Table 3.2).

Table 3.2: Descriptive data and subscales of the parental questionnaire

	NUMBER OF ITEMS	MEDIAN	MEAN (SD*)
Total scale	31	16.2	19.3 (6.1)
Oral symptom	6	4.9	4.6 (1.6)
Functional limitations	8	5.4	4.9 (1.6)
Emotional well-being	7	5.9	5.1 (1.4)
Social well-being	10	5.6	4.7 (1.5)

*Standard Deviation

3.6.2.2. The child's overall oral health and wellbeing

The first question after the child's information was "How would you rate the health of your child's teeth, lips, jaws and mouth?" The most common response was "Good" (60%), but no parent responded with "Excellent". The second question was

"How much is your child's overall wellbeing affected by the condition of his/her teeth, lips, jaws or mouth?" The majority (50%) of parents responded with "Very little" and none replied "Very much" (see Table 3.3).

Table 3.3: Child's overall oral health and wellbeing

1. How would you rate the health of your child's teeth, lips, jaws and mouth?	**Poor (%)**	**Fair (%)**	**Good (%)**	**Very good (%)**	**Excellent (%)**
	1 (5)	3 (15)	12 (60)	4 (20)	0 (0)
2. How is your child's general wellbeing affected by the condition of his/her teeth, lips, jaws and mouth?	**Very much (%)**	**A lot (%)**	**Some (%)**	**Very little (%)**	**Not at all (%)**
	0 (0)	2 (10)	7 (35)	10 (50)	1 (5)

3.6.2.3. Questions related to child's oral symptoms

Concerning oral symptom, respondents most often answered "Never" or "I don't know". For example, when asked how often the child had difficulty in saying words, or gum bleeding, 80% and 70% of parents respectively responded "Never"; and in response to an item about mouth breathing, 45% responded "I don't know". On many items, the response "Sometimes" was also frequent. For example, when asked about food caught in or between the teeth and difficulty in drinking or eating hot or cold foods, 50% of the parents gave this answer. By contrast, very few responses of "Often" were recorded (30% to Q3 and 5% to Q10) and no one responded with "Every day" to any item (Table 3.4).

Table 3.4: Responses to items related to oral symptoms (%)

	I don't know	Every day	Often	Sometimes	Once or twice	Never
3. Pain in his/her teeth, lips, or jaws?	0	0	30	25	35	10
4. Gum bleeding?	5	0	0	10	15	70
5. Mouth ulcer?	30	0	0	5	15	50
6. Bad breath?	10	0	0	35	0	55
7. Food stuck in the floor of his mouth?	30	0	0	25	5	40
8. Food stuck between his/her teeth?	10	0	0	50	15	25
9. Difficulty in chewing some food such as apples, corn or meat?	5	0	0	50	5	40
10. Mouth breathing?	45	0	5	20	5	25
11. Sleeping difficulty?	5	0	0	20	25	50
12. Difficulty in pronouncing some words?	10	0	0	5	5	80
13. Taking more time in eating?	30	0	0	15	5	50

3.6.2.4. Questions related the child's Functional limitation

The majority of respondents answered "Never" in the section on functional limitation. For instance, 65% of parents said "Never" to questions 19,23 and 24, while 60% did so for questions 16. In addition, 45 responded "Never" to Q 17,20 and 25. There were also quite high responded for "I don't know" and "Sometimes", for instance, 50% and 40% of parents responded for Q21 and Q25 respectively. There were correspondingly no responses of "Every day" (Table 3.5).

Table 3.5: Results of response items related to Functional limitation (%)

	Don't know	Every day	Often	Sometimes	Once or twice	Never
14. Difficulty in eating or drinking cold or hot food?	5	0	0	50	5	40
15. Difficulty in eating what he/she prefers	20	0	0	25	15	40
16. Eating only some kinds of food such as soft food?	5	0	0	10	25	60
17. Upset or anxiety?	10	0	0	20	25	45
18. Depression or nervousness?	5	0	5	20	15	55
19. Worries or fear?	10	0	5	20	0	65
20. Absence from school because of an appointment, pain, or a surgery on his mouth or teeth?	5	0	0	15	35	45
21. Difficulty in concentration at school?	50	0	0	5	0	45
22. Did not want to speak or read aloud in school?	35	0	0	15	0	50
23 Did not want to talk to other children?	20	0	0	15	0	65
24. Avoided smiling or laughing with other children?	15	0	0	20	0	65
25. Became less healthy than other children?	5	0	5	40	5	45

3.6.2.5. Questions related the child's Emotional well-being

The majority of parents responded to items in the section (Emotional well-being) with "Never". For instance, all questions in this section had at least 50% or more of "Never" responses, except Q34, where the figure were 30%. Many parents also responded "Sometimes"; for example 35% did so to Q32 and Q34. The number of parents responding "I don't know" were small 20% or less. Finally only 5% of parents were responded with "Every day" and that for Q29 (Table 4.6).

Table 3.6: Results of response items related to Emotional well-being (%)

	Don't know	Every day	Often	Sometimes	Once or twice	Never
26. Worried that he/she is different from other children?	5	0	0	20	10	65
27. Felt that the others are more beautiful than him/her?	5	0	0	0	5	90
28. Acted shamefully or embarrassed?	0	0	0	10	0	90
29. Named by perplexed titles?	5	5	0	5	5	80
30. Refused by other children?	20	0	0	10	0	70
31. Did not want to sit with other children?	20	0	0	0	0	80
32. Did not want to participate in activities such as sports, trips, public celebrations?	5	0	0	35	10	50
33. Worried because he/she has few friends?	10	0	0	10	5	75
34. Cared about what people said about his/her mouth, jaws, lips or teeth?	10	0	20	35	5	30

3.6.2.6. Questions related to the child's Social well-being

Again, the majority of parents responded to items in the section on social wellbeing with "Never". For instance, all questions in this section had at least 55% of "Never" responses, except Q44, where the figure was 35%. Many parents also responded "Sometimes"; for example 35% and 30% did so to items 45 and 48 respectively. The number of parents responding "I don't know" or "Often" were correspondingly small, at 15% or less, except for Q47 (30%). Finally, no parents replied "Every day" to any question in this section (see Table 3.7).

Table 3.7: Results of response items related to Social well-being (%)

	I don't know	Every day	Often	Sometimes	Once or twice	Never
35. Asked by other children about his/her teeth, mouth, lips or jaws?	25	0	0	15	0	60
36. Upset?	10	0	0	30	10	50
37. Irregular sleeping?	5	0	0	25	5	65
38. Guilty?	15	0	0	15	10	60
39. Absence from work because of pain, an appointment, or surgery on teeth?	10	0	0	10	25	55
40. Less time for him/her in his family?	5	0	5	15	20	55
41. Worried because the child will have less opportunity than others in work life?	5	0	5	5	5	80
42. Uncomfortable feeling in public places such as markets and parks?	5	0	0	20	10	65
43. Jealousy of you or one of the family members?	10	0	0	5	0	85
44. Blamed by you or one of the family members?	5	0	5	35	20	35
45. Discussion with you or one of the family members?	5	0	10	30	0	55
46. Required more attention from you or others in the family?	10	0	15	25	0	50
47. Conflict on a family occasion?	5	0	30	5	5	55
48. Disagreement between families?	5	0	0	30	10	55
49. Financial difficulties in the family?	10	0	0	10	0	80

3.6.3. Findings from the children's perspective questionnaire

3.6.3.1. Descriptive data and subscale of the children's questionnaire

In the children's questionnaire, there were 25 items, with overall median, mean and SD scores of 18.4, 17.3 and 3.2 respectively. There were 5 questions about the child's oral symptoms, for which the respective figures were 4.2, 4.1 and 0.9. For the five questions about the child's functional limitation they were 4.6, 4.3 and 0.96 respectively, while for the five questions about emotional wellbeing the median was 5 and the SD 0.72. Finally, there were ten questions about social wellbeing with parents and others, with a median of 4.6 and SD of 0.73 (Table 3.8).

Table 3.8: Descriptive data and subscales of the children's questionnaire

	NUMBER OF ITEMS	MEDIAN	MEAN (SD)
Total scale	25	18.4	17.3 (3.2)
Oral symptom	10	4.2	4.1 (0.9)
Functional limitations	5	4.6	4.3 (0.96)
Emotional well-being	4	5	4.6 (0.72)
Social well-being	6	4.6	4.3 (0.73)

3.6.3.2 Questions about the child's overall oral health and wellbeing

The first question on overall oral health was "What do you think about the health condition of your teeth and mouth?", to which 40% of children responded "OK" and 50% "Good", while none said "Poor". The second question was "How much do your teeth or mouth trouble your health in everyday life?" Here, 35% said "Sometimes" and 45% "Not at all", while 10% each responded "A lot" and "Not at all" (Table 3.9).

Table 3.9: Child's overall oral health and wellbeing

1. What do you think about the health condition of your teeth and mouth?	**Poor (%)**	**O K (%)**	**Good (%)**	**Very good (%)**
	0 (0)	8 (40)	10 (50)	2 (10)
2. How much do your teeth or mouth trouble your health in everyday life?	**A lot (%)**	**Sometimes (%)**	**A little (%)**	**Not at all (%)**
	2 (10)	7 (35)	9 (45)	2 (10)

3.6.3.3 Questions about the child's Oral symptoms

When asked about oral symptoms, the majority of children responded "Sometimes", "Once or twice" or "Never". For instance, 75% and 35% of children responded "Once or twice" to items 5 and 7 respectively, while 80% said "Never" to item 6 and 65% to item 9. Responses of "Every day" and "Often" were correspondingly rare. To question 5, for example, only 15% responded "Every day" and 5% "Often" (Table 3.10).

Table 3.10: Results of response items related to Oral symptoms (%)

	EVERY DAY	OFTEN	SOMETIMES	ONCE OR TWICE	NEVER
5. Pain in your mouth or teeth?	0	15	10	75	0
6. Painful spots in your mouth?	5	5	5	5	80
7. Pain in your teeth because of hot or cold drink?	0	10	45	35	10
8. Food stuck in your teeth?	0	0	55	5	40
9. Bad breath?	0	0	30	5	65

3.6.3.4. Questions about the child's Functional limitations

The majority of children responded "Never" to items related to functional limitations. For instance, 65%, 85% and 65% did so in response to items 10, 13 and 14 respectively, while no child were respond "Every day" to a question in this section. There were relatively few responses of "Once or twice", which accounted for no more than 30% in response to any question in this section (Table 3.11).

Table 3.11: Results of response items related to Functional limitation (%)

	EVERY DAY	**OFTEN**	**SOMETIMES**	**ONCE OR TWICE**	**NEVER**
10. Need more time to eat?	0	0	30	5	65
11. Difficulty in chewing some food such as apple or corn?	0	10	55	20	15
12. Refuse to eat preferred food?	0	0	40	30	30
13. Difficulty in pronouncing some words?	0	0	15	0	85
14. Difficulty in sleeping?	0	5	20	10	65

3.6.3.5. Questions about the child's Emotional wellbeing

Most children responded "Never" or "Sometimes" to items regarding their emotional wellbeing. For instance, 90% and 85% responded "Never" to items 16 and 17 respectively, while 30% said "Sometimes" to Q19. Correspondingly, 35% of children

responded “Often” to Q18 and there were only 5% answers of “Every day” in this section (Table 3.12).

Table 3.12: Results of response items related to Emotional well-being (%)

	EVERY DAY	OFTEN	SOMETIMES	ONCE OR TWICE	NEVER
15. Feel upset?	0	0	25	20	55
16. Feel frustrated?	0	0	5	5	90
17. Been ashamed?	5	5	5	0	85
18. Concerned what other people think about your teeth or mouth?	0	35	20	5	40
19. Worried that you do not have a good appearance?	0	0	30	10	60

3.6.3.6. Questions about the child’s Social wellbeing

Many children responded “Never” or “Sometimes” to questions concerning their social wellbeing. In fact, these two categories accounted for at least 85% of responses to all items in this section, with “Never” predominating. There were correspondingly few responses of “Often” in this section (one child to each of three items) and no one said “Every day” at all (Table 3.13).

Table 3.13: Results of response items related to Social well-being (%)

	EVERY DAY	OFTEN	SOMETIMES	ONCE OR TWICE	NEVER
20. Absent from school?	0	0	0	30	70
21. Had difficulty doing your homework?	0	5	15	10	70
22. Could not concentrate in class?	0	0	35	5	60
23. Don’t want to speak or read aloud?	0	0	5	5	90
24. Avoid laughing or smiling with other children?	0	5	15	0	80
25. Avoid speaking with other children?	0	5	5	0	90
26. Avoid playing with other children?	0	5	20	10	65
27. Avoid participating in group activities with other children?	0	0	55	5	40
28. Named by perplexed titles?	0	0	0	10	90
29. Asked by other children about your teeth or mouth?	0	0	5	25	70

3.7. Summary and conclusion of study one

This study was undertaken to develop cross-cultural equivalent versions of the CPQ8-10 and PPQ6-14. This was achieved by translation, back-translation and a small-scale study of cultural equivalence. The equivalence of the scale was tested against the dimensions outlined by Guillemin et al (1993). Semantic equivalence was achieved by translation and back-translation, which produced a stable version of the questionnaire. Idiomatic equivalence was ensured when the translated version was reviewed by two independent panels of experts as well as parents and children. Experiential equivalence was established by pretesting the questionnaire, while conceptual equivalence was achieved by means of qualitative interviews. The score means and psychometric properties of the Arabic version were similar to those for the original parental and child questionnaires developed by Jokovic et al (2003) and Jokovic et al (2004) respectively. In conclusion, the Arabic versions of the CPQ8-10 and P-CPQ developed in study one exhibited cross-cultural equivalence according to the criteria provided by Guillemin et al (1993).

4. VALIDATION OF DEVELOPMENT OF THE ARABIC VERSION OF CPQ8-10

4.1. Introduction

The key issue in the conception of health-related quality of life and accordingly of oral health-related quality of life is the shift in the perception of health from merely the absence of disease and infirmity to complete physical, mental and social wellbeing, in line with the definition of health by the World Health Organisation (WHO, 1948). It is now widely accepted that health assessment should include measurement of physical, social and psychological functions, as well as quality of life. OHRQoL includes components such as function, pain, psychological components and social aspects (Locker, 1988). By contrast, Locker refers to the "serious limitations" of clinical measures of the normative needs of oral health care: "they tell us nothing about the functioning of either the oral cavity or the person as a whole and nothing about subjectively perceived symptoms such as pain and discomfort". However, the impact of both general and oral health on the quality of life has received more attention in recent years. OHRQoL assessments are used in research, surveys and studies evaluating the outcome of oral care (McGrath and Bedi, 2002; Locker et al, 2004).

OHRQoL measures have three broad uses, according to Locker (1996). First, they can be used for political purposes, to demonstrate the effects of oral disorders to policy makers. Second, they can have theoretical value in developing and testing models of oral and general health. Thirdly, the measures can be put to practical use in research to best meet our needs for planning and evaluating the treatment of individuals. McGrath et al (2004) note that determining the OHRQoL might also be useful in planning public dental health policies in order to evaluate the outcomes of dental care and treatment. Furthermore, OHRQoL is an essential factor in oral health surveys, clinical research and studies that evaluate the outcomes of preventive and therapeutic programmes intended to develop the oral health status of individuals or populations.

4.2. Aims of the study

The present study had three aims:

- To evaluate and assess the validity and reliability of the Arabic versions of the CPQ8-10 and PPQ6-14 questionnaires among Saudi children aged 8-10 years and their parents respectively.
- To compare the OHRQoL of Saudi children and their parents with those of their counterparts in England.
- To explore how children from different cultures respond to similar OHRQoL instruments.

4.3. Materials and methods

4.3.1. Study design

A cross-sectional epidemiological survey was undertaken in Saudi Arabia and the England. The Saudi sites were a general dental practitioner clinic at a primary health care centre (PHCC), a paediatric dental clinic at a dental centre (DC) and the Oral and Maxillofacial Department at King Fahad Hospital Hofuf in Alhasa (KFHH). In England, the survey was undertaken at the Dental Institute in Denmark Hill and in community clinics. Similar procedures were followed for the two samples, in order to make possible a comparison between them. The selection of the Saudi study methods was affected by site-specific issues, so modifications were made to the British study, to minimise differences.

4.3.2. Subject group

The survey recruited a consecutive series of 75 children aged 8 to 10 years and their parents, who attended the three dental clinics mentioned above (PHCC, DC and KFHH) in Alhasa, in the Eastern Region of Saudi Arabia. The children were free from any systemic disease. Their parents were asked to complete the Parental Perception Questionnaire (P-CPQ). A further 75 children were recruited from the Dental Clinic at Denmark Hill and community clinics in England.

4.3.3. Sampling

According to Jokovic et al (2004, Table 4), the mean total CPQ scores for participants who gave an overall rating of their wellbeing as ‘not affected’ was 11.3 (SD 6.7), while for those affected ‘some/ a little bit’ the mean was 22.4 (SD 13.4). In

order to detect a similar effect in the present sample using the usual assumptions of significance of 0.05 and power of 50%, a minimum sample size of 21 was required in each group. Given that there were likely to be twice as many participants in the 'some/a little bit' group, 75 children were recruited in order to obtain approximately 25 in the 'not affected' group.

Thus, 75 children and their parents were recruited in Saudi Arabia and another 75 children were recruited in England. This gave a total sample of 150 children for study two, ensuring that the required sample size would be obtained (Table 4.1).

Table 4.1: Composition of sample for study two

Sites of Clinics		Number of Children	Total
Saudi Arabia	Primary Health Care Centre	25	
	Hospital (KFHH)	25	75
	Dental Centre	25	
England	Hospital-Paediatric Specialist	25	
	Hospital- Casualty	25	75
	Community	25	

The sample in each country was composed of convenience samples of male and female children. The inclusion criteria were: age between 8 and 10 years; seeking treatment at a dental clinic at one of the specified locations. Children were excluded if they were mentally retarded or did not read Arabic if recruited in Saudi Arabia, or English if recruited in England. Children who had received full mouth treatment under general anaesthesia in the last three months were also excluded.

4.3.4. Questionnaires

The Arabic version of the child questionnaire for measuring OHRQoL in 8-10 year-old children and the P-CPQ developed in study one were administered to the Saudi sample, while the standard Canadian versions for children (Appendix 13) and the parents (Appendix 12) developed by Jokovic et al (2004) and by Jokovic et al. (2003) respectively were used in the English part of the study.

Before the survey began, all staff members involved were informed about the study, because it was considered essential that everyone involved, including administrators and patients, were knowledgeable about the project and supportive of it. A

standardised protocol was applied when administrating the questionnaires. This required the researcher to be present in the waiting area of each clinic in order to offer assistance, to ensure confidentiality and independence and to explain the questionnaire if necessary.

4.3.4.1. The child questionnaire

The CPQ8-10 child OHRQoL questionnaire consisted of 25 questions organized into five sections: on the child's overall oral health and wellbeing (2 items), on the child's oral health symptoms (5 items), on the child's functional limitation (5 items), on the child's emotional well-being (5 items) and on the child's social well-being (10 items).

The first section was designed to produce global ratings of the child's oral health and the extent to which his/her oral/orofacial condition affected his/her overall wellbeing. Question three (Q3) was worded as follows: "What do you think about your teeth or mouth? Would you say that they are…?" The response format was a four-point scale from "very good" = 0 to "poor" = 3. Q4 read: "How much do your teeth or mouth trouble your health in everyday life?" The four possible responses ranged from "not at all" = 0 to "a lot" = 3.

The other four sections (2 to 5) of the questionnaire asked: "During the last four weeks, because of a problem in your teeth, mouth or jaws, how often have you had...?" in relation to the child's oral/orofacial condition. The response options and scores were: "never" (scoring 0), "once or twice" (1), "sometimes" (2), "often" (3) and "every day" (4).

Each child was asked to complete the CPQ8-10 in the dental clinic waiting room just prior to the dental examination. At this time the examiner and the parent of the child were seated with him/her in order to explain or clarify unclear questions, especially for 8-year-olds.

4.3.4.2. The parental questionnaire

The parental questionnaire (P-CPQ6-14) consisted of 49 questions organized into four sections: on the child's overall oral health and wellbeing (2 items),), on the

child's oral health symptoms (11 items), on the child's functional limitation (12 items), on the child's emotional well-being (9 items) and on the child's social well-being (15 items).

Questions in the first section, concerning the global rating of the child's oral health and the extent to which his/her oral/orofacial condition affected his/her overall wellbeing, were worded as follows. Q1: "How would you rate the condition of your child's teeth or mouth?" This had a five-point response format, ranging from "excellent" = 0 to "poor" = 4. Q2: "How much is your child's overall wellbeing affected by the condition of his/her teeth, lips, jaws and mouth?" This also had a five-point response format, ranging from "not at all" = 0 to "very much" = 4.

The other four sections of the questionnaire asked the parents: "During the last three months, because of a problem in the child's teeth, mouth or jaws, how often did your child have the following?" The response options and scores were as follows: "never" (scoring 0), "once or twice" (1), "sometimes" (2), "often" (3) and "every day" (4). There was also the option of responding "I don't know".

4.3.5. Clinical examination

An examination of the children's oral health condition was collected at the time of their routine dental visits to the three Saudi dental clinics, but there was no clinical examination in English part of the study.

4.3.6. Clinical equipment

The examination was conducted under the examination lamp that is normally used in a dental clinic. The examiner was seated behind the subject, who was on a dental chair or a normal chair as circumstances allowed. All necessary steps were taken to prevent cross-infection during the examination by using a fresh set of sterilised instruments and a new pair of gloves (latex allergy free) for each participant. The following instruments were used: a plane mouth mirror, a blunt ball-ended probe and cotton rolls and gauze.

4.3.7. Recording

The examiner was accompanied by a volunteer recorder from the PHCC, for whom training was provided. For each subject, the same recording procedures and a validated recording chart were used (Appendix 14).

4.3.8. Oral examination

The dental examination was conducted in a standard order according to the BASCD diagnostic criteria for caries prevalence (Pitts et al, 1997): upper right, upper left, lower left, lower right and for each tooth: distal, occlusal or incisal, mesial, buccal and lingual.

The sequence of the examination was as follows:

a) Examination of the tooth condition (dental caries), using primary and permanent (decayed/missing/filled surface: dmfs/DMFS) tooth surface index scores.
b) Gingival condition.
c) Trauma of the upper and lower incisors.
d) Dental erosion of the upper incisors.
e) Dental anomalies.
f) Dental opacity of the two upper anterior incisors.

4.3.8.1. Dental caries

Data were recorded by tooth surface (using anatomical boundaries) where appropriate. The diagnosis of the condition of tooth surfaces was visual and the ball-ended probe was used only for the removal of debris or to assist in the detection of sealants. The categories and criteria described below are the basic requirements relevant to this level of the BASCD guidelines.

- **Surface code 0 (or G) – Present and sound**

  A surface was recorded as sound if it showed no evidence of treatment or untreated clinical caries at the ‘caries into dentine’ diagnostic threshold. The early stages of caries, as well as other similar conditions, were excluded. Thus, surfaces with the following defects, in the absence of other positive criteria, were recorded as present and sound: white or chalky spots, a discoloured or rough spot, stained pits or fissures in the enamel that were not associated with a carious lesion into dentine and dark, shiny, hard, pitted areas of enamel in a

tooth showing signs of moderate to severe fluorosis. All questionable lesions were coded as ‘sound’.

- **Surface code 1 – Arrested dentinal decay**
  Surfaces were regarded as falling into this category if, in the opinion of the trained examiner, after inspection there was arrested caries in dentine.

- **Surface code 2 – Decayed**
  Surfaces were recorded in this category if, in the opinion of the examiner, after visual inspection there was a carious lesion in dentine.

- **Surface code 3 – Decay with pulpal involvement**
  Surfaces were regarded as falling into this category if, in the opinion of the trained examiner, there was a lesion that involved the pulp, necessitating extraction or pulp treatment.

- **Surface code 4 – Filled and decayed**
  A surface having a filling and a carious lesion, whether or not the lesion(s) were in physical association with the restoration(s), fell into this category unless the lesion was so extensive as to be classified as ‘decay with pulpal involvement’, in which case the fillings were ignored and the surface was classified as code 3.

- **Surface code 5 (or F) – Filled with no decay**
  Surfaces containing a satisfactory permanent restoration (excluding crowns and bridge abutments) of any material were coded under this category (with the exception of obvious sealant restorations, which were coded separately as N).

Absent teeth – children

- **Surface code 6 – Extracted due to caries**
  Surfaces were regarded as missing if the tooth had been extracted because it was carious. Surfaces which were absent for other reasons were not included in this category. Missing deciduous canines and deciduous molars were included.

- **Tooth code 7 – Extracted for orthodontic reasons**

  Surfaces were regarded as extracted for orthodontic reasons if the tooth had in the opinion of the examiner been extracted solely for orthodontic reasons. Unless there was overwhelming evidence to the contrary, missing first permanent molars were recorded as extracted due to caries.

  Note: Only those teeth extracted for caries were included in the 'missing' element of the DMFS index. Orthodontic extractions were not counted; this category is included here only to clarify the coding with respect to first permanent molars.

- **Tooth code 8 (U) - Unerupted**

  The permanent tooth was unerupted, congenitally absent or missing for unknown reasons and no deciduous tooth was present in the space.

- **Tooth code 9 – Excluded**

  When the examiner was unable to form a judgement on the state of a surface, e.g. because more than half of it was obscured by orthodontic bands, code 9 was used.

- **Surface code R – Filled, needs replacing (not carious)**

  A filled surface was regarded as falling into this category if, in the opinion of the examiner after inspection, it was chipped or cracked and needed replacing but there was no caries into the dentine present on the same surface. Lesions or cavities containing a temporary dressing, or cavities from which a restoration had been lost, were regarded as 'filled, needs replacing' unless there was also evidence of caries into dentine, in which case they were coded in the appropriate category of 'decayed'.

  Sealed surfaces

  The ball-ended probe was used to assist in the detection of sealant. Care was taken to differentiate sealed surfaces from those restored with tooth-coloured filling materials used in prepared cavities that had defined margins and no evidence of fissure sealant (the latter were regarded as fillings and were coded 5

(or F), 4 (or R). Sealant codes were used when the surface contained evidence of sealant (including cases with partial loss of sealant), otherwise it was coded as sound when the tooth did not contain an amalgam or conventional tooth-coloured filling.

- **Surface code S - Sealed surface, type unknown**

  This was used for all occlusal, buccal and lingual surfaces containing, in the opinion of the examiner, some type of fissure sealant, but where no evidence of a defined cavity margin could be seen. This included both preventive and therapeutic sealants.

- **Surface code N – Obvious sealant restoration**

  Code N was used for all occlusal, buccal and lingual surfaces containing, in the opinion of the examiner, a sealant restoration where there was evidence of a defined cavity margin and a sealed unrestored fissure. (If doubt existed as to whether a preventive sealant or a sealant restoration was present, the surface was regarded as being preventively sealed – code S).

- **Surface code C – Crown/advanced restorative procedures**

  This code was used for all surfaces which had been permanently crowned or received a permanent item of advanced restorative care in the form of a veneer or a restoration constituting a bridge abutment, irrespective of the materials employed or the reasons leading to the placement of the crown/veneer/bridge.

  Note that missing teeth replaced by a bridge were coded 6, 7, 8 all surfaces T children). In addition, the number of teeth (and surfaces) coded S, N and C were separately identifiable. When ‘decayed’ and ‘filled’ results were required, ‘decayed’ comprised codes 1 + 2 + 3 + 4 and ‘filled’ comprised codes 5(F) + R + N.

- **Surface code T – Trauma**

  Surfaces affected by trauma fell into this category. Such surfaces were coded T whether or not the missing tooth substance had been replaced with a restoration.

Whenever it was necessary to explicitly record *teeth* lost through trauma, additional computing was used. *Surfaces* affected by trauma were coded T.

According to Do and Spencer (2007), caries experience data were recorded and the prevalence of caries calculated using primary and permanent (dmfs/DMFS) tooth surfaces index scores. The data were then used to classify the children into four groups: 0, 1-2, 3-4 and 5+ dmft/DMFS.

4.3.8.2. Gingival examination

The gingival condition and the presence or absence of calculus was recorded according to the criteria of O'Brien (1994). For this assessment, each jaw was divided into three segments as follow:

- Left and right extending backwards from distal surfaces of canines to the distal surfaces of the most posterior teeth present. This means that the segment included the area around teeth d and/or e, if they were present in the mouth.
- The middle segment, extending forwards from distal surface of the canine on one side around to the distal surface of the canine on the other side. This means that the segment included the area around the upper and lower (upper left, upper middle, upper right, lower right, lower middle and lower left) anterior teeth.

The examiner looked at each of these segments in the prescribed order. The examinations were carried out three times, one to assess the gum condition, then for the assessment of plaque and the last time to determine the presence or absence of calculus. The average condition of the gums or plaque in the segment was recorded and the worst area in that segment was recorded. When there was any doubt about the classification of any condition, the lower category was recorded.

The gingival condition was evaluated by examining the gum, plaque and calculus of subjects.

(a) Gums

Each segment was examined both buccally and lingually and a statement was recorded according to one of the following categories:

- **Code 0** The gums appear healthy. (No treatment is needed).
- **Code 1** The gums are not healthy.
- **Code 9** Assessment cannot be made.

Note: Code 1 included both gingivitis that could be reversed by prophylaxis and improved oral hygiene and more severe redness and swelling of the gums.

(b) Plaque

Each segment was examined visually both buccally and lingually, and its condition was coded according to one of the following categories:

- **Code 0** The teeth appear clean.
- **Code 1** Plaque visible without probing.
- **Code 9** Assessment cannot be made.

Note: A probe was not used for this part of the examination, except for removing small pieces of food found around the teeth.

(c) Calculus

Each segment was examined visually and the presence of calculus was recorded as follows:

- **Code 0** No calculus.
- **Code 1** Calculus is present.
- **Code 9** Assessment cannot be made.

4.3.8.3. Trauma of permanent incisors

Upper and lower incisors were examined for traumatic injury according to the scheme of O'Brien (1994):

- **Code 0** No trauma.
- **Code 1** Discolouration.
- **Code 2** Fracture involving enamel.
- **Code 3** Fracture involving enamel and dentine.

- **Code 4** Fracture involving enamel, dentine and pulp.
- **Code 5** Missing due to trauma.
- **Code 6** Restoration such as glass ionomer, composite or stainless-steel crown.
- **Code 7** Permanent replacement including crown, denture and bridge.
- **Code 8** Temporary restoration.
- **Code 9** Assessment cannot be made.

4.3.8.4. Erosion

The buccal and lingual surfaces of the maxillary incisor teeth were assessed for loss of surface enamel characteristics, and/or exposure of dentine or pulp and coded according to O'Brien (1994). The incisal edge was considered and each surface was coded using the following criteria:

- **Code 0** Normal
- **Code 1** Enamel only – loss of surface characterization
- **Code 2** Enamel and dentine – loss of enamel, exposing dentine
- **Code 3** Enamel into pulp – loss of enamel and dentine resulting in pulpal exposure
- **Code 9** Assessment cannot be made.

4.3.8.5. Enamel opacity

Subjects were examined from in front. Enamel opacities were defined as defects involving an alteration in the translucency of the enamel and variable in degree. The examination was carried out on the two upper anterior teeth and recorded according to the criteria of O'Brien (1994):

- **Code 0** No opacity.
- **Code 1** Demarcated opacity, the defective enamel being of normal thickness with a smooth surface. It could be white, cream, yellow or brown in colour. Some maintain a surface translucency while others are dull in appearance.
- **Code 2** Diffused opacity, the defective enamel being of normal thickness and during eruption having a nearly smooth surface and being white in colour. It could have a linear, patchy and confluent appearance.

- **Code 3** Hypoplasia, when a defect involves the surface of the enamel and is associated with reduced localised thickness of enamel. It appears as pits or grooves, single or multiple, deep or shallow and narrow or wide. The enamel of reduced thickness may be translucent or opaque.

If there was any doubt about the presence of a defect, the tooth surface was scored as normal.

4.3.8.6. Oral anomalies

Any defects of cleft lip and/or palate or any other craniofacial anomalies were coded according to O'Brien (1994).

- **Code 0** None
- **Code 1** Present – specified in comments section in the recording chart.

4.3.9. Training and calibration

Inter-examiner reproducibility was verified during calibration of a BASCD survey of 5- year-olds in October 2005 in Dewsbury, West Yorkshire. The results of calibration were 0.93, 0.97 and 0.84 for sensitivity, specificity and kappa respectively (Appendix 15). These results met the BASCD requirements.

4.3.10. Ethical approval

Ethical approval for conducting the research was sought from the Directorate of Health Affairs in Alhasa (Appendix 1). In addition, ethical approval for the English part of the study was obtained from the National Research Ethics Services (King's College Hospital Research Committee) REF: 09/H0808/62 (Appendix 16). Data were collected anonymously and strict confidentiality was guaranteed at all stages of the research.

4.3.11. Informed consent

Informed consent was obtained from each child's parent for interviews and clinical examination (Appendix 3) and (Appendix 17) for the Saudi and England site respectively, after they had read the patient information sheet (Appendix 5) for the Saudi site and (Appendix 18) for the England site.

4.3.12. Data analysis and psychometric properties

The SPSS software program (version 17.0) was used for data analysis. Descriptive statistics for all variable data were used to summarize the clinical examination and the questionnaire results. Construct validity was measured by means of correlations between the scale scores and the global indicators of oral health and overall wellbeing. Discriminative validity was assessed by calculating the correlation of the total scores between all three group in the PHCC, DC and KFHH clinics. This was assessed by assuming that the children from the hospital group had poorer OHRQoL than the PHCC group, while the children from the DC group had scores lying between these two. The significance of the differences between means was assessed by ANOVA.

The construct validity of the scales was further assessed by comparing the mean scores of groups defined by the impact of their oral health on their global wellbeing as ‘not affected’ versus ‘affected some/ a little’. The internal consistency of the scale and subscales was assessed by means of Cronbach’s alpha, scores of 0.6 or more showing good to excellent reliability (Locker and Slade 1993).

5. RESULTS OF VALIDATION OF ARABIC VERSION OF CPQ8-10

5.1. Demographic characteristics for study two

Table 5.1 summarises the demographic characteristics of the participants in study two in terms of clinical group, gender, age and relationship to the accompanied child. The income categories were devised on the basis of quartiles of national incomes. Thus the ranges were devised to place the population into four equal groups on the basis of their income. Data on national income for the UK was taken from www.economicsonline.co.uk for 2007 and from MOE&P (2005) for the Saudi Arabia.

Table 5.1: Demographic characteristics of participants in Saudi Arabia and the United Kingdom in study two

A. Saudi sites

	Primary Health Care Centre	**Dental Centre**	**King Fahad Hospital**	**TOTAL (%)**
No. of cases	25	25	25	75
Male	14	11	12	37 (49)
Female	11	14	13	38 (51)
Accompanied by father	10	13	13	36 (48)
Accompanied by mother	13	9	8	30 (40)
Accompanied by other	2	3	4	9 (12)
Children aged 8 years	7	7	7	21 (28)
Children aged 9 years	6	9	6	21(28)
Children aged 10 years	12	9	12	33 (44)
House holder income				
Up to 36.000 SR	7	3	3	13 (17)
More than 36.000 SR to 72.000 SR	10	11	9	30 (40)
More than 72.000 SR to 120,000 SR	7	7	8	22 (29)
More than 120.000 SR	1	4	5	10 (14)

Table 5.1 continued

	Community clinic	Hospital site (Paedodontic)	Hospital (Casualty)	TOTAL (%)
No. of cases	25	25	25	75
Male	12	11	13	36 (48)
Female	13	14	12	39 (52)
Accompanied by father	15	18	17	50 (67)
Accompanied by mother	7	7	5	19 (25)
Accompanied by other	3	0	3	6 (8)
Children aged 8 years	9	8	6	23 (31)
Children aged 9 years	10	7	8	25 (33)
Children aged 10 years	6	10	11	27 (36)
House holder income				
Up to £20,000	7	5	4	16 (21)
More than £20,000 to £23,000	12	17	13	42 (56)
More than £23,000 to £30,000	6	3	8	17 (23)
More than £30,000	0	0	0	0 (0)

5.2.Responses to questionnaires in Saudi Arabia and England

Table 5.2: Saudi children's oral health and wellbeing on the child questionnaire

	Very good N (%)	Good N (%)	OK N (%)	Poor N (%)
Q.3. What do you think about the health condition of your teeth and mouth?	16 (21)	24 (32)	24 (32)	11 (15)
	Not at all N (%)	**A little bit N (%)**	**Sometimes N (%)**	**A lot N (%)**
Q 4. How much do your teeth or mouth trouble your health in everyday life?	15 (20)	26 (35)	21 (28)	13 (17)

At baseline, Table 5.2 represents the oral health and wellbeing of the Saudi children. Twenty-four of the participants (32%) rated their oral health condition as good and 11 (15%) as poor. Responses for how much the teeth troubled children in everyday life were 26 (35%) for ‘a little bit’ and 13 (17%) for ‘a lot’.

Table 5.3 shows the distribution of items according to the severity response in the CPQ8-10 child questionnaire in the Saudi sites: the majority of children responded to all items, but responses were uneven. For instance, 50% or more responded ‘never’ on all questions except for questions 8 and 9, where 17.3% and 45.3% respectively said ‘never’. The numbers responding ‘once or twice’ were also high; for example, 37.3% did so for questions 8 and 20, while for other questions between 6% and 28% did so. Responses of ‘sometimes’ and ‘often’ were correspondingly low, ranging from 1.3% to 14.7%, while fewer than 6% responded ‘daily or almost every day’ to any item.

Table 5.3: Distribution of items according to the severity response in the CPQ8-10 child questionnaire in Saudi sites

	Never N (%)	Once or twice N (%)	Sometimes N (%)	Often N (%)	Daily or almost every day N (%)
Questions about oral symptoms					
5. Pain in your mouth or teeth?	33 (44)	21 (28)	14 (19)	3 (4)	4 (5)
6. Painful spots in your mouth?	42 (56)	20 (27)	8 (11)	3 (4)	2 (3)
7. Pain in your teeth because of hot or cold drink?	39 (52)	13 (17.3)	17 (22.7)	5 (6.7)	1 (1.3)
8. Stuck food in your teeth?	13 (17.3)	28 (37.3)	24 (32.0)	6 (8.0)	4 (5.3)
9. Bad breath?	34 (45.3)	23 (30.7)	14 (18.7)	3 (4.0)	1 (1.3)
Questions about functional limitations					
10. Need more time to eat?	45 (60.0)	9 (12.0)	16 (21.3)	4 (5.3)	1 (1.3)
11. Difficulty in chewing some food such as apple or corn?	42 (56.0)	18 (24.0)	9 (12.0)	4 (5.3)	2 (2.7)
12. Refuse to eat preferred food?	48 (64.0)	14 (18.7)	8 (10.7)	3 (4.0)	2 (2.7)
13. Difficulty in pronouncing some words?	50 (66.7)	17 (22.7)	6 (8.0)	2 (2.7)	0 (0)
14. Difficulty in sleeping?	51 (68)	12 (16.0)	10 (13.3)	1 (1.3)	1 (1.3)
Questions about emotional well-being					
15. Feel upset?	42 (56)	16 (21.3)	8 (10.7)	6 (8)	3 (4)
16. Feel frustrated?	47 (62.7)	16 (21.3)	7 (9.3)	5 (6.7)	0 (0)
17. Been ashamed?	55 (73.3)	6 (8)	10 (13.3)	4 (5.3)	0 (0)
18. Been concerned what other people think about your teeth or mouth?	47 (62.7)	18 (24)	9 (12)	1 (1.3)	0 (0)
19. Worried that you are not have good appearance?	52 (69.3)	13 (17.3)	5 (6.7)	4 (5.3)	1 (1.3)
Questions about social well-being					
20. Absent from school?	39 (52)	28 (37.3)	6 (8)	2 (2.7)	0 (0)
21. Had difficulty doing your homework?	58 (77.3)	12 (16)	3 (4)	2 (2.7)	0 (0)

Table 5.3 continued

22. Could not concentrate in classroom?	53 (70.7)	11 (14.7)	6 (8)	5 (6.7)	0 (0)
23. Don't want to speak or read loudly?	57 (76)	11 (14.7)	4 (5.3)	3 (4)	0 (0)
24. Avoid laughing or smiling with other children?	55 (73.3)	8 (10.7)	6 (8)	4 (5.3)	2 (2.7)
25. Avoid speaking with other children?	55 (73.3)	10 (13.3)	8 (10.7)	2 (2.7)	0 (0)
26. Avoid playing with other children?	61 (81.3)	5 (6.7)	6 (8.0)	2 (2.7)	1 (1.3)
27. Avoid participating in group activities with other children?	55 (73.3)	10 (13.3)	7 (9.3)	2 (2.7)	1 (1.3)
28. Called mocking names?	57 (76)	12 (16)	4 (5.3)	1 (1.3)	1 (1.3)
29. Asked by other children about your teeth or mouth?	40 (53.3)	21 (28)	11 (14.7)	3 (4)	0 (0)

5.2.1. Saudi Parental questionnaires

Table 5.4 shows the Saudi children's oral health and wellbeing on the P-CPQ. At baseline, 23 parents (30%) rated the oral health condition of their children as good, 18 (24%) as poor and only 4 (5.3%) as excellent. With respect to the children's overall wellbeing being affected by the condition of their teeth or mouth, 24 (32%) replied 'some', 13(17.3) 'very much' and only 7 (9.3%) 'not at all'.

Table 5.4: Children's oral health and wellbeing in Saudi site

	Excellent N (%)	**Very good N (%)**	**Good N (%)**	**Fair N (%)**	**Poor N (%)**
1. How do you evaluate your child's teeth, lips jaws, and mouth health?	4 (5.3)	12 (16)	23 (30)	18 (24)	18 (24)
	Not at all N (%)	**Very little N (%)**	**Some N (%)**	**A lot N (%)**	**Very much N (%)**
2. How is your child's general wellbeing affected by the condition of his/her teeth, lips, jaws, and mouth?	7 (9.3)	14 (18.7)	24 (32)	17 (22.7)	13 (17.3)

Similarly, the distribution of items according to severity of response in the P-CPQ parent questionnaire in the Saudi sites is shown in Table 5.5. The predominant response was 'never/don't know', which ranged between 33% and 85.2% of respondents, to Q6 and Q22 respectively. Responses of 'once or twice', 'sometimes' and 'often' varied between 2.7% and 33% for Q35 and Q20 respectively. However,

responses of ‘daily or almost every day’ were very low, from 0% to 5.3%, to Q20 and Q3 respectively, with the very marked exception of Q40 (46.7%).

Table 5.5: Distribution of items according to severity of response in the P-CPQ parent questionnaire in Saudi sites

	Never/ don't know N (%)	Once or twice N (%)	Sometimes N (%)	Often N (%)	Daily or almost every day N (%)
Questions about oral symptoms					
3. Pain in his teeth, lips, or jaws?	25 (33.3)	22 (29.3)	13 (17.3)	11 (14.7)	4 (5.3)
4. Gum bleeding?	39 (52)	19 (25.3)	10 (13.3)	6 (8)	1 (1.3)
5. Mouth ulcer?	37 (49.3)	21 (28.0)	11 (14.7)	5 (6.7)	1 (1.3)
6. Bad breath?	33 (44)	19 (25.3)	19 (25.3)	2 (2.7)	2 (2.7)
7. Food stuck in the floor of his mouth?	36 (48)	13 (17.3)	16 (21.3)	7 (9.3)	3 (4)
8. Food stuck between his/her teeth?	31 (41.3)	22 (29.3)	13 (17.3)	8 (10.7)	1 (1.3)
9. Difficulty in chewing some food such as apple, corn, or meat?	35 (46.7)	16 (21.3)	16 (21.3)	6 (8.0)	2 (2.7)
10. Mouth breathing?	30 (40)	23 (30.7)	16 (21.3)	4 (5.3)	2 (2.7)
11. Sleeping difficulty?	32 (42.7)	20 (26.7)	13 (17.3)	8 (10.7)	2 (2.7)
12. Difficulty in pronouncing some words?	46 (61.3)	13 (17.3)	7 (9.3)	6 (8.0)	3 (4)
13. Taking more time in eating?	47 (62.7)	14 (18.7)	9 (12)	4 (5.3)	1 (1.3)
Questions about functional limitations					
14. Difficulty in eating or drinking cold or hot food?	44 (58.7)	15 (20)	11 (14.7)	2 (2.7)	3 (4)
15. Difficulty in eating what he/she prefers?	33 (44)	22 (29.3)	15 (20)	4 (5.3)	1 (1.3)
16. Eating only some kind of food such as soft food?	36 (48)	22 (29.3)	14 (18.7)	3 (4)	0 (0)
17. Upset or anxious?	35 (46.7)	19 (25.3)	15 (20)	4 (5.3)	2 (2.7)
18. Depression or nervousness?	36 (48)	19 (25.3)	14 (18.7)	4 (5.3)	2 (2.7)
19. Worries or fear?	32 (42.7)	21 (28)	15 (20)	5 (6.7)	2 (2.7)
20. Absence from school because of an appointment, pain, or surgery on his mouth or teeth?	34 (45.3)	25 (33.3)	13 (17.3)	3 (4)	0 (0)
21. Difficulty in concentration at school?	39 (52)	17 (22.7)	13 (17.3)	3 (4)	3 (4)
22. Does not want to speak or read aloud at school?	64 (85.3)	0 (0)	9 (12)	2 (2.7)	0 (0)
23 Does not want to talk to other children?	57 (76)	3 (4)	8 (10.7)	7 (9.3)	0 (0)
24. Avoids smiling or laughing with other children?	56 (74.7)	3 (4)	13 (17.3)	3 (4)	0 (0)
25. Has become less healthy than other children?	33 (44)	16 (21.3)	23 (30.7)	1 (1.3)	2 (2.7)
Questions about emotional wellbeing					
26. Worried that he is different from other children?	26 (34.7)	19 (25.3)	22 (29.3)	6 (8)	2 (2.7)
27. Feels that others are more beautiful than him?	49 (65.3)	16 (21.3)	4 (5.3)	5 (6.7)	1 (1.3)
28. Acts shamefully or embarrassed?	55 (73.3)	6 (8)	11 (14.7)	3 (4)	0 (0)
29. Called mocking names?	49 (65.3)	5 (6.7)	10 (13.3)	9 (12)	2 (2.7)
30. Rejected by other children?	61 (81.3)	3 (4)	11 (14.7)	0 (0)	0 (0)
31. Does not want to sit with other children?	59 (78.7)	6 (8)	6 (8)	4 (5.3)	0 (0)
32. Does not want to participate in activities such as sports, trips, public celebrations?	39 (52)	21 (28)	13 (17.3)	0 (0)	2 (2.7)
33. Worried because he has few friends?	46 (61.3)	7 (9.3)	15 (20)	6 (8)	1 (1.3)
34. Cares about what people say about his mouth, jaws, lips, or teeth?	45 (60.)	10 (13.3)	17 (22.7)	3 (4)	0 (0)
Questions about social wellbeing					
35. Asked by other children about his teeth, mouth, lips, or jaws?	47 (62.7)	5 (6.7)	20 (26.7)	2 (2.7)	1 (1.3)
36. Upset?	48 (64)	9 (12.)	14 (18.7)	4 (5.3)	0 (0)
37. Irregular sleeping?	44 (58.7)	9 (12)	17 (22.7)	2 (2.7)	3 (4)
38. Guilty?	44 (58.7)	7 (9.3)	18 (24)	5 (6.7)	1 (1.3)
39. Absence from work because of pain, an appointment, or surgery on teeth?	36 (48.)	21 (28)	12 (16)	5 (6.7)	1 (1.3)
40. Less time for him in his family?	35 (46.7)	19 (25.3)	14 (18.7)	7(9.3)	35 (46.7)
41. Worried because the child will have less opportunity than others in working life?	48 (64)	17 (22.7)	7 (9.3)	3 (4)	0 (0)
42. Uncomfortable feeling in public places such as markets and parks?	32 (42.7)	18 (24)	21 (28)	4 (5.3)	0 (0)
43. Jealous of you or one of the family members?	45 (60)	16 (21.3)	14 (18.7)	0 (0)	0 (0)
44. Blamed by you or one of the family members?	41 (54.7)	12 (16)	19 (25.3)	3 (4)	0 (0)
45. Discussion with you or one of the family members?	37 (49.3)	13 (17.3)	23 (30.7)	2 (2.7)	0 (0)
47. Conflict during a family occasion?	30 (40)	15 (20)	18 (24)	12 (16)	0 (0)
48. Disagreement between families?	32 (42.7)	14 (18.7)	16 (21.3)	11 (14.7)	2 (2.7)
49. Financial difficulties in the family?	48 (64)	10 (13.3)	9 (12)	6 (8)	2 (2.7)

5.2.2. Results for the English child questionnaire

Table 5.6 shows the overall and 'bother' ratings of oral health condition for the CPQ8-10 in the English site. The overall condition was rated by 25 children (33.3%) as good, by 31 (41.3%) as OK and by 9 (12%) as poor, while the trouble caused by the teeth in everyday life was rated by 34 children (45.3%) as 'a little bit', by 22 (29.3) as 'not at all' and by 9 (12%) as 'a lot'.

Table 5.6: Child's oral health and wellbeing in the England site

	Very good N (%)	**Good N (%)**	**OK N (%)**	**Poor N (%)**
3. What do you think about health condition of your teeth and mouth?	10 (13.3)	25 (33.3)	31 (41.3)	9 (12)
	Not at all N (%)	A little bit N (%)	Sometimes N (%)	A lot N (%)
4. How much do your teeth or mouth trouble your health in everyday life?	22 (29.3)	34 (45.3)	10 (13.3)	9 (12)

Table 5.7 shows the distribution of items according to the severity responses to the CPQ8-10 child questionnaire in the English sites. The most common response of the children was 'never', ranging from 14.7% (Q8) to 89.3% (Q26). The next most frequent responses were 'once or twice', from 5.3% (Q10) to 38.7 (Q20) and 'sometimes', from 4% (Q 25) to 34.7% (Q8), followed by 'often', from 0% (Q26) to 9.3% (Q8) and 'daily or almost every day', from 0% (Q28) to 6.7% (Q8).

Table 5.7: Distribution of items according to the severity response in the CPQ8-10 child questionnaire in the England

	Never N (%)	Once or twice N (%)	Sometimes N (%)	Often N (%)	Daily or almost every day N (%)
Questions about oral symptoms					
5. Pain in your mouth or teeth?	33 (44)	21 (28)	13 (17.3)	4 (5.3)	4 (5.3)
6. Painful spots in your mouth?	40 (53.3)	23 (30.7)	7 (9.3)	3 (4.)	2 (2.7)
7. Pain in your teeth because of hot or cold drink?	40 (53.3)	11 (14.7)	18 (24)	5 (6.7)	1 (1.3)
8. Food stuck in your teeth?	11 (14.7)	26 (34.7)	26 (34.7)	7 (9.3)	5 (6.7)
9. Bad breath?	35 (46.7)	21 (28)	15 (20)	3 (4)	1 (1.3)
Questions about functional limitations					
10. Need more time to eat?	51 (68)	4 (5.3)	14 (18.7)	3 (4)	3 (4)
11. Difficulty in chewing some food such as apple or corn?	42 (56)	17 (22.7)	9 (12)	5 (6.7)	2 (2.7)
12. Refuse to eat preferred food?	51 (68)	11 (14.7)	7 (9.3)	3 (4)	3 (4)
13. Difficulty in pronouncing some words?	56 (74.7)	13 (17.3)	4 (5.3)	1 (1.3)	1 (1.3)
14. Difficulty in sleeping?	55 (73.3)	10 (13.3)	8 (10.7)	1 (1.3)	1 (1.3)
Questions about emotional wellbeing					
15. Feel upset?	43 (57.3)	16 (21.3)	9 (12)	5 (6.7)	2 (2.7)
16. Feel frustrated?	51 (68)	11 (14.7)	8 (10.7)	5 (6.7)	0 (0)
17. Been ashamed?	60 (80)	3 (4)	7 (9.3)	4 (5.3)	1 (1.3)
18. Been concerned what other people think about your teeth or mouth?	54 (72)	10 (13.3)	7 (9.3)	2 (2.7)	2 (2.7)
19. Worried that you do not have a good appearance?	56 (74.7)	9 (12)	3 (4)	5 (6.7)	2 (2.7)
Questions about social wellbeing					
20. Absent from school?	38 (50.7)	29 (38.7)	5 (6.7)	2 (2.7)	1 (1.3)
21. Had difficulty doing your homework?	65 (86.7)	8 (10.7)	1 (1.3)	1 (1.3)	0 (0)
22. Could not concentrate in classroom?	60 (80)	7 (9.3)	6 (8)	2 (2.7)	0 (0)
23. Don't want to speak or read aloud?	62 (82.7)	9 (12)	2 (2.7)	2 (2.7)	0 (0)
24. Avoid laughing or smiling with other children?	61 (81.3)	7 (9.3)	3 (4)	1 (1.3)	3 (4)
25. Avoid speaking with other children?	64 (85.3)	6 (8)	3 (4)	2 (2.7)	0 (0)
26. Avoid playing with other children?	67 (89.3)	5 (6.7)	3 (4)	0 (0)	0 (0)
27. Avoid participating in group activities with other children?	65 (86.7)	6 (8.0)	3 (4)	1 (1.3)	0 (0)
28. Called mocking names?	65 (86.7)	5 (6.7)	4 (5.3)	1 (1.3)	0 (0)
29. Asked by other children about your teeth or mouth?	47 (62.7)	20 (26.7)	6 (8.0)	1 (1.3)	1 (1.3)

5.2.3. English parental questionnaire

Table 5.8 shows parents' responses regarding children's oral health and wellbeing on the P-CPQ questionnaire at the English sites. Their oral health condition was rated by 30 parents (40%) as good, by 17 (22.7%) as fair and by only 3 (4%) as excellent. With respect to the child's overall wellbeing as affected by the condition of his or her teeth or mouth, 22 (29.3%) replied 'some', 16 (21.3%) 'not at all' and only 4 (5.3%) 'very much'.

Table 5.8: Frequency and percentage of England parents' responses regarding children's overall health and overall wellbeing

	Excellent N (%)	**Very good N (%)**	**Good N (%)**	**Fair N (%)**	**Poor N (%)**
1. How do you evaluate your child's teeth, lips jaws, and mouth health?	3 (4)	17 (22.7)	30 (40)	17 (22.7)	7 (9.3)
	Not at all N (%)	**Very little N (%)**	**Some N (%)**	**A lot N (%)**	**Very much N (%)**
2. How is your child's general wellbeing affected by the condition of his/her teeth, lips, jaws, and mouth?	16 (21.3)	28 (37.3)	22 (29.3)	5 (6.7)	4 (5.3)

Table 5.9 represents the distribution of items according to the severity response on the P-CPQ parent questionnaire in England. The predominant response was 'never/don't know', which ranged between 24% for Q8 and 88% for Q26. Responses of 'once or twice' and 'sometimes' varied, mainly between 8% (Q48) and 38.7% (Q18). However, there were few responses of 'often' or 'daily or almost every day', from 0% on Q11 and Q14 to 14.7% for Q3.

Table 5.9: Distribution of items according to the severity response on the P-CPQ parent questionnaire in England

	Never/ don't know N (%)	Once or twice N (%)	Sometimes N (%)	Often N (%)	Daily/or almost every day N (%)
Questions about oral symptoms					
3. Pain in his teeth, lips, or jaws?	22 (29.3)	24 (32)	15 (20)	11 (14.7)	3 (4)
4. Gum bleeding?	45 (60)	16 (21.3)	8 (10.7)	3 (4)	3 (4)
5. Mouth ulcer?	36 (48)	21 (28)	11 (14.7)	5 (6.7)	2 (2.7)
6. Bad breath?	28 (37.3)	14 (18.7)	27 (36)	4 (5.3)	2 (2.7)
7. Food stuck in the floor of his mouth?	41 (54.7)	14 (18.7)	12 (16)	5 (6.7)	3 (4)
8. Food stuck between his/her teeth?	18 (24)	28 (37.3)	23 (30.7)	5 (6.7)	1 (1.3)
9. Difficulty in chewing some food such as apple, corn, or meat?	38 (50.7)	13 (17.3)	18 (24)	4 (5.3)	2 (2.7)
10. Mouth breathing?	48 (64)	7 (9.3)	11 (14.7)	4 (5.3)	5 (6.7)
11. Sleeping difficulty?	43 (57.3)	16 (21.3)	14 (18.7)	2 (2.7)	0 (0)
12. Difficulty in pronouncing some words?	60 (80)	5 (6.7)	6 (8)	4 (5.3)	0 (0)
13. Taking more time in eating?	42 (56)	13 (17.3)	12 (16)	5 (6.7)	3 (4)
Questions about functional limitations					
14. Difficulty in eating or drinking cold or hot food?	46 (61.3)	9 (12)	17 (22.7)	3 (4)	0 (0)
15. Difficulty in eating what he/she prefers?	50 (66.7)	10 (13.3)	12 (16)	2 (2.7)	1 (1.3)
16. Eating only some kind of food such as soft food?	55 (73.3)	8 (10.7)	10 (13.3)	2 (2.7)	0 (0)
17. Upset or anxious?	32 (42.7)	25 (33.3)	15 (20)	3 (4)	0 (0)
18. Depression or nervousness?	36 (48)	29 (38.7)	8 (10.7)	2 (2.7)	0 (0)
19. Worries or fear?	45 (60)	18 (24)	9 (12)	3 (4)	0 (0)
20. Absence from school because of an appointment, pain, or a surgery in his mouth or teeth?	30 (40)	33 (44)	11 (14.7)	1 (1.3)	0 (0)
21. Difficulty in concentration at school?	60 (80)	7 (9.3)	6 (8)	2 (2.7)	0 (0)
22. Does not want to speak or read aloud at school?	61 (81.3)	7 (9.3)	5 (6.7)	2 (2.7)	0 (0)
23 Does not want to talk to other children?	64 (85.3)	5 (6.7)	5 (6.7)	1 (1.3)	0 (0)
24. Avoids smiling or laughing with other children?	55 (73.3)	12 (16)	5 (6.7)	3 (4)	0 (0)
25. Has become less healthy than other children?	56 (74.7)	10 (13.3)	8 (10.7)	1 (1.3)	0 (0)
Questions about emotional wellbeing					
26. Worried that he is different from other children?	66 (88)	2 (2.7)	6 (8)	1 (1.3)	0 (0)
27. Feels that others are more beautiful than him?	60 (80)	7 (9.3)	7 (9.3)	1 (1.3)	0 (0)
28. Acts shamefully or embarrassed?	52 (69.3)	11 (14.7)	12 (16)	0 (0)	0 (0)
29. Called mocking names?	57 (76)	6 (8)	9 (12)	1 (1.3)	2 (2.7)
30. Rejected by other children?	62 (82.7)	6 (8)	6 (8)	1 (1.3)	0 (0)
31. Does not want to sit with other children?	64 (85.3)	4 (5.3)	5 (6.7)	2 (2.7)	0 (0)
32. Does not want to participate in activities such as sports, trips, public celebrations?	62 (82.7)	5 (6.7)	6 (8)	2 (2.7)	0 (0)
33. Worried because he has few friends?	59 (78.7)	5 (6.7)	7 (9.3)	3 (4)	1 (1.3)
34. Cares about what people say about his mouth, jaws, lips, or teeth?	48 (64)	16 (21.3)	7 (9.3)	3 (4)	1 (1.3)
Questions about social wellbeing					
35. Asked by other children about his teeth, mouth, lips, or jaws?	51 (68)	10 (13.3)	11 (14.7)	3 (4)	0 (0)
36. Upset?	45 (60)	16 (21.3)	9 (12)	4 (5.3)	1 (1.3)
37. Irregular sleeping?	50 (66.7)	15 (20)	7 (9.3)	3 (4)	0 (0)
38. Guilty?	49 (65.3)	10 (13.3)	11 (14.7)	4 (5.3)	1 (1.3)
39. Absence from school because of pain, an appointment, or surgery in teeth?	36 (48)	25 (33.3)	11 (14.7)	3 (4)	0 (0)
40. Less time for him in his family?	55 (73.3)	9 (12)	9 (12)	2 (2.7)	0 (0)
41. Worried because the child will have less opportunity than others in work life?	62 (82.7)	6 (8)	7 (9.3)	0 (0)	0 (0)
42. Uncomfortable feeling in public places such as markets and parks?	60 (80)	4 (5.3)	11 (14.7)	0 (0)	0 (0)

Table 5.9 continued

43. Jealous of you or one of the family members?	63 (84)	6 (8)	3 (4)	3 (4)	0 (0)
44. Blamed by you or one of the family members?	61 (81.3)	7 (9.3)	6 (8)	1 (1.3)	0 (0)
45. Discussion with you or one of the family?	56 (74.7)	9 (12)	7 (9.3)	3 (4)	0 (0)
47. Conflict with a family occasion?	59 (78.7)	8 (10.7)	6 (8)	2 (2.7)	0 (0)
48. Disagreement between families?	60 (80)	9 (12)	6 (8)	0 (0)	0 (0)
49. Financial difficulties in the family?	57 (76)	10 (13.3)	7 (9.3)	1(1.3)	0 (0)

5.3 . Psychometric properties of study two

5.3.1. Overall scales and subscales for Saudi Arabia and England

Table 5.10 represents the overall scores of total scales and subscales for Saudi Arabia and England. There were no significant differences in OHRQoL for children's and parents' questionnaires in the two national samples (all $p > 0.05$), except for the subscale of social wellbeing in the child questionnaire, where there was a significant difference ($p= 0.018$).

Table 5.10: Mean (SD) and Median values for CPQ 8-10 and P-CPQ 6-14 scales for Saudi Arabia and England samples: study two

	SAUDI ARABIA	**ENGLAND**	
Child questionnaires	**Mean (SD) Median**	**Mean (SD) Median**	**P ***
Total scale	15.76 (11.16) 14	13.83 (12.57) 13	0.32
Subscales			
Oral symptoms	5.00 (3.38) 3	5.04 (3.47) 4	0.95
Functional limitation	3.15 (3.34) 3	2.91 (3.60) 3	0.67
Emotional well-being	2.97 (3.33) 4	2.77 (3.83) 4	0.73
Social well-being	4.64 (3.75) 4	3.11 (4.07) 4	0.018
Parent questionnaires			
Total scale	21.05 (14.02) 17	19.24 (14.39) 16	0.43
Subscales			
Oral symptoms	6.71 (4.26) 4.5	6.19 (4.26) 4	0.45
Functional limitation	5.79 (5.24) 5	5.37 (5.37) 4.5	0.62
Emotional well-being	3.24 (3.13) 5	2.87 (2.83) 4	0.44
Social wellbeing	5.32 (4.95) 6	4.81 (4.97) 5	0.52

* Kruskall Wallis

5.3.2. Discriminant validity

As expected, in the Saudi locations the overall mean scores were higher in the hospital group and lower in the PHCC group for both children's and parental questionnaires, with p-values of 0.002 and 0.009 respectively (Table 6.11). Furthermore, the hospital group had higher mean scores for all four subscales in children and parents. The difference was significant for children's functional limitation (p=0.006) and social wellbeing (p<0.001), while for parents the difference was significant in the social wellbeing subscale (p=0.001) (Table 5.11).

Table 5.11: Discriminant validity: comparison between PHC, DC and hospital group mean scores for children and their parents in Saudi sites

Scale scores	**PHC (N= 25)**	**Dental Centre (N= 25)**	**Hospital (N= 25)**		
Children	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**	**F**	**p**
Overall scale	10.12 (6.88)	16.28 (10.70)	20.88 (12.71)	6.76	0.002
Subscales					
Oral symptoms	3.88 (2.83)	5.36 (3.23)	5.76 (3.83)	2.22	0.116
Functional limitation	1.80 (1.95)	2.92 (2.72)	4.72 (4.32)	5.45	0.006
Emotional wellbeing	1.92 (2.50)	3.36 (4.01)	3.64 (3.17)	1.97	0.147
Social wellbeing	2.52 (1.92)	4.64 (3.79)	6.76 (4.00)	9.90	< 0.001
Parents					
Overall scale	16.28 (8.33)	19.16 (13.93)	27.72 (16.38)	4.99	0.009
Subscales					
Oral symptoms	5.64 (3.53)	6.88 (4.36)	7.60 (4.72)	1.37	0.261
Functional limitation	4.48 (3.59)	5.04 (5.50)	7.84 (5.89)	3.12	0.050
Emotional wellbeing	2.48 (1.78)	3.24 (3.14)	4.00 (4.32)	1.49	0.232
Social wellbeing	3.68 (3.95)	4.00 (4.19)	8.28 (5.35)	7.99	0.001

The overall mean scores in England were significant for CPQ8-10 and CPQ, with p=0.011 and 0.001 respectively. Children and their parents in the casualty clinic reported greater impact on OHRQoL than children in the paediatric dental clinic and community clinic. The mean score and standard deviation values were 18.12 (13.97), 15.36 (13.60) and 8.00 (7.05) for children and 26.68 (16.37), 18.92 (14.36) and 12.12 (7.36) for parents respectively (Table 5.12).

By clinical group, significant differences were found in subscale mean scores of children in functional limitation and social wellbeing, with p-values of 0.006 and 0.029 respectively. However, for parents, significant differences were found in the subscales of oral symptoms, functional limitation and social wellbeing, with p-values of 0.038, 0.012 and < 0.001 respectively (Table 5.12).

Table 5.12: Discriminant validity: Comparison between community and hospital groups (paediatric and casualty clinic) mean scores for children and their parents in English sites

Scale scores	**Community clinic**	**Dental Hospital (paediatric dental clinic)**	**Dental Hospital (casualty clinic)**	**F**	**P**
Children	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**		
overall scale	8.00 (7.05)	15.36 (13.60)	18.12 (13.97)	4.78	0.011
Subscales					
Oral symptoms	4.00 (3.29)	5.36 (3.24)	5.76 (3.83)	1.81	0.172
Functional limitation	1.32 (1.87)	2.88 (3.48)	4.52 (4.35)	5.56	0.006
Emotional wellbeing	1.28 (2.44)	3.48 (4.46)	3.56 (3.97)	3.02	0.055
Social wellbeing	1.40 (1.47)	3.64 (5.35)	4.28 (3.90)	3.73	0.029
Parents	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**	**F**	**P**
overall scale	12.12 (7.36)	18.92 (14.36)	26.68 (16.37)	7.54	0.001
Subscales					
Oral symptoms	4.52 (3.11)	6.52 (4.46)	7.52 (4.65)	3.42	0.038
Functional limitation	3.20 (3.08)	5.28 (6.10)	7.64 (5.64)	4.71	0.012
Emotional wellbeing	2.04 (1.69)	3.16 (3.11)	3.40 (3.33)	1.68	0.195
Social wellbeing	2.36 (2.93)	3.96 (4.18)	8.12 (5.63)	11.49	< 0.001

5.3.3 Reliability

Cronbach's alpha values for the Saudi sample as a whole were 0.86 and 0.90 for children and their parents respectively, indicating high internal consistency (Table 5.13). The subscales represented moderate to high internal consistency reliability, which ranged from 0.56 for social wellbeing to 0.75 for emotional wellbeing in children, while for parents it ranged from 0.50 for emotional wellbeing to 0.85 for social wellbeing.

Table 5.13: Reliability statistics for Saudi sample

	Children		**Parents**	
	No. of items	**Cronbach's alpha (N= 75)**	**No. of items**	**Cronbach's alpha (N= 75)**
Total scale	25	0.86	31	0.90
Subscales				
Oral symptoms	5	0.65	6	0.66
Functional limitation	5	0.74	8	0.78
Emotional wellbeing	5	0.75	7	0.50
Social wellbeing	10	0.56	10	0.85

Cronbach's alpha for the English sample as a whole was 0.91 for children and their parents, indicating very high internal consistency (Table 5.14). The subscales represented moderate to high internal consistency reliability, which ranged from 0.68 for oral symptoms to 0.83 for emotional wellbeing in children, while for parents it ranged from 0.46 for emotional wellbeing to 0.85 for social wellbeing.

Table 5.14: Reliability statistics for English sample

	Children		**Parents**	
	No. of items	**Cronbach's alpha (N= 75)**	**No. of items**	**Cronbach's alpha (N= 75)**
Total scale	25	0.91	31	0.91
Subscales				
Oral symptoms	5	0.68	6	0.74
Functional limitation	5	0.77	8	0.82
Emotional wellbeing	5	0.83	7	0.46
Social wellbeing	10	0.79	10	0.85

5.3.4. Construct validity

Spearman's correlation (rho) between global rating indicators and the Saudi CPQ8-10 (children) for overall scale and subscales was not significant (all p-values >0.05) and ranged from low to moderate (Table 5.15). However, the Spearman's correlation for the Saudi P-CPQ (parents) was significant for global rating of oral health in the overall scale (rho= 0.37, p-value= 0.001). There was also a significant correlation in subscale scores between oral symptoms and overall wellbeing (rho = 0.05, p-value = 0.048), oral health and functional limitation (rho = 0.30, p-value = 0.01) and between oral health and social wellbeing (rho = 0.27, p-value = 0.021) (Table 5.15).

Table 5.15: Construct validity - Rank correlation between scores and global ratings of oral health and overall wellbeing, Saudi site

Scale scores	**Oral health**		**Overall wellbeing**	
Saudi children	**rho**	**P**	**rho**	**P**
Total scale	0.13	0.765	0.21	0.06
Subscales				
Oral symptoms	0.13	0.91	0.24	0.038
Functional limitation	0.11	0.399	0.16	0.152
Emotional wellbeing	0.10	0.552	0.11	0.396
Social wellbeing	0.11	0.361	0.18	0.134
Saudi parents	**rho**	**P**	**rho**	**P**
Total scale	0.26	0.023	0.18	0.123
Subscales				
Oral symptoms	0.15	0.146	0.05	0.048
Functional limitation	0.30	0.01)	0.11	0.355
Emotional wellbeing	0.12	0.033	0.14	0.550
Social wellbeing	0.27	0.021	0.23	0.05

In the English part of the study, the correlation between global indicators and the CPQ8-10 was positive and significant overall and for subscales (Table 5.16). Similarly, the Spearman's correlation for the P-CPQ was significant for the overall scale, with global ratings for oral health of rho = 0.35, p-value = 0.002 and overall wellbeing of rho = 0.29, p-value = 0.01.). The correlations for subscales were not significant in oral symptoms and overall wellbeing (rho = 0.18, p-value = 0.104), emotional wellbeing and oral health (rho = 0.18, p = 0.104) and overall wellbeing (rho = 0.13, p = 0.91), also the correlation was not significant with the overall wellbeing indicator (rho = 0.11, p = 0.46) (Table 5.16).

Table 5.16: Construct validity - Rank correlation between scores and global ratings of oral health and overall wellbeing, English sites

Scale scores	**Oral health**		**Overall wellbeing**	
CPQ 8-10	**rho**	**P**	**rho**	**P**
Total scale	0.37	0.001	0.55	< 0.001
Subscales				
Oral symptoms	0.35	0.002	0.52	< 0.001
Functional limitation	0.28	0.015	0.36	0.001
Emotional wellbeing	0.36	0.001	0.51	< 0.001
Social wellbeing	0.24	0.038	0.48	< 0.001
P-CPQ	**rho**	**P**	**rho**	**P**
Total scale	0.35	0.002	0.29	0.01
Subscales				
Oral symptoms	0.29	0.012	0.18	0.104
Functional limitation	0.34	0.003	0.21	0.038
Emotional wellbeing	0.13	0.912	0.11	0.469
Social wellbeing	0.39	< 0.001	0.39	< 0.001

5.3.5. Summary and conclusion

The results show that the overall scale and subscale scores for the two settings (Saudi Arabia and England) were nearly similar, with no significant differences in children and parents except in the subscale of social wellbeing in the child questionnaire. The overall scale scores for child questionnaires had a pattern similar to that reported by recent studies conducted in Brazil (Martins et al, 2009) in children with a cavitated caries; in Denmark (Wogelius et al, 2009) in children with amelogenesis imperfecta and multiple dental agenesis; in children with fluorosis in Mexico (Aguilar-Diaz et al, 2011); in public school children in Brazil (Ramos-Jorge et al, 2011) and children with dental caries and malocclusion in Iran (Jabarifar et al, 2011). However they were better than those reported by Jokovic et al (2004) in children with dental caries and children with clefts of the lip and palate; by Martins et al (2009) in patient with dental caries and malocclusion in Brazil; by Barbosa et al (2009) in children with dental caries, gingivitis, flourosis and malocclusion in Brazil; by Barbosa and Gaviao (2012) in children with dental caries, flourosis, gingivitis and malocclusion in Brazil and by Sardenberg et al (2013) in children with dental caries and malocclusion in Brazil. But they were poorer than findings by Wogelius et al (2009) in a healthy children group in Brazil and by Do and Spencer (2008) in children with dental caries and malocclusion in an Australian. This variation might be explained by the fact that some items will have received different responses according to the oral health status of the children, their education, race and culture.

The overall scale scores for the parental questionnaire were comparable with the Canadian study (Jokovic et al, 2003), but higher than those reported in the South Australian study (Do and Spencer, 2008). This may be due to the fact that the Australian study was conducted among a general population sample, while the present study recruited dental clinic patients.

Frequency distributions for all variables are given as appendices (Appendix 19). The frequency distributions suggest that the scale scores are skewed in most cases. Therefore non-parametric tests (kruskall Wallis) were used to compare groups.

Skewed data are common in measures of OHRQoL (Locker 1998; Slade 2002). The analyses were designed to check for the validity of the scale, it was hypothesised that

individuals from the hospital centre would report greater impact (poorer OHRQoL) than those attending the Primary Dental Centre. Similarly it was hypothesised that the presence of clinical symptoms, such as decay and gingivitis would be associated with poorer OHRQoL.

5.4. Relationship of oral health and quality of life in the Saudi study site

Tables 5.17 and 5.18 report the mean domain scores and overall scores for CPQ8-10 and P-CPQ 6-14 respectively, according to the groups' experience of caries, gingival condition, trauma, erosion and opacities. These tables should be interpreted with caution for two reasons. Firstly the proportion of participants with these clinical conditions is small in some cases, for example only 7% of the sample have a dmft/DMFT equal to or less than five. Thus the sample size may not be sufficiently powered to detect differences in OHRQoL between groups defined by clinical conditions. Second, clustering of clinical conditions may occur such that individuals may have more than one clinical problem thus making it difficult to isolate the individual effect of clinical state on OHRQoL.

As expected, the highest mean values were recorded for oral symptoms, followed by social wellbeing, then functional limitation and emotional wellbeing. The overall domain scores of the OHRQoL were highest in the children with opacities, followed by erosion, then gingival condition and caries. The results for the parental questionnaire were similar.

There was no consistent pattern of overall scores and domain scores for caries condition, gingival condition, trauma, erosion and opacities among children or their parents. Generally, children who had poor oral health status tended to report higher OHRQoL scores than children who were free from dental diseases. This difference was not significant for any oral health condition, including caries, gingival condition, trauma, erosion and opacities, with the exception that there was a significant difference in the P-CPQ in dental caries for overall score and the functional limitation subscale ($p<0.05$). There was also a significant difference for the subscale score for oral symptoms of opacities ($p< 0.05$).

Table 5.17: Mean domain scores and overall scale score for OHRQoL reported by children on caries, gingival condition, trauma, erosion and opacities on Saudi site

	Sample number (%)	Oral symptoms	Functional limitations	Emotional wellbeing	Social wellbeing	Overall scale
Children response		**Mean (SD) Median**	**Mean (SD) Median**	**Mean (SD) Median**	**Mean (SD) Median**	**Mean (SD) Median**
Caries *						
0-5 dmft/DMFT	5 (6.7)	5.8 (3.0) 8	2.0 (1.8) 2	2.8 (2.2) 2	2.4 (1.8) 3	13.0 (6.6) 15
>0-5 dmft/DMFT	70 (93.3)	4.9 (3.4) 4.5	3.2 (3.4) 2	2.9 (3.4) 1.5	4.8 (3.8) 4	15.9(11.4) 12.5
t- test		0.546	0.793	0.120	1.391	0.570
p		0.587	0.431	0.905	0.169	0.571
Gingival condition *						
Healthy gum 0	28 (37.3)	5.6 (2.5) 5.5	3.4 (2.9) 2	2.3 (2.5) 1	4.0 (3.6) 3	15.5 (9.6) 13
Unhealthy gum 1	47 (62.7)	4.6 (3.7) 4	2.9 (3.5) 2	3.3 (3.6) 2	5.0 (3.8) 5	15.9(12.0) 12
t- test		1.278	0.562	1.169	1.078	0.155
P		0.205	0.576	0.246	0.285	0.877
Trauma condition *						
No trauma 0	37 (49.3)	4.8 (2.7) 5	3.1 (2.8) 2	2.7 (3.1) 1	4.7 (3.5) 4	15.4 (8.9) 13
Trauma present 1	38 (50.7)	5.1 (3.9) 4	3.2 (3.8) 2	3.2 (3.6) 2	4.5 (3.9) 4	16.1(13.1) 11.5
t- test		0.340	0.235	0.692	0.326	0.271
p		0.735	0.815	0.491	0.746	0.788
Erosion *						
No erosion 0	53 (70.7)	4.9 (3.2) 4	2.9 (3.0) 2	2.9 (2.9) 2	4.7 (4.0) 4	15.5(11.1) 12
Erosion present 1	22 (29.3)	5.1 (3.7) 5	3.7 (4.0) 2.5	3.1 (4.1) 1.5	4.6 (3.0) 4	16.4 (11.5)15
t- test		0.075	0.893	0.272	0.140	0.323
P		0.941	0.375	0.787	0.889	0.748
Opacities *						
No opacities 0	63 (84)	4.9 (3.4) 4	3.1 (3.4) 2	3.0 (3.4) 2	4.7 (3.8) 4	15.7(11.5) 12
Opacities present	12 (16)	5.6 (3.2) 5	3.5 (3.2) 3.5	2.7 (2.8) 1.5	3.4 (3.4) 4	16.0 (9.8) 14
t- test		0.650	0.398	0.346	0.391	.081
P		0.518	0.692	0.730	0.697	0.936

* Children may have had more than one clinical condition.

Table 5.18: Mean domain scores and overall scale score for OHRQoL reported by Parents on caries, gingival condition, trauma, erosion and opacities on Saudi site

	Sample number (%)	Oral symptoms	Functional limitations	Emotional wellbeing	Social wellbeing	Overall scale
Parent response		**Mean (SD) Median**	**Mean (SD) Median**	**Mean (SD) Median**	**Mean (SD) Median**	**Mean (SD) Median**
Caries *						
0-5 dmft/DMFT	5 (6.7)	4.8 (2.7) 3	3.2 (2.7) 4	2.4 (1.1) 2	6.0 (0.7) 6	16.4 (3.4) 17
>0-5 dmft/DMFT	70 (93.3)	6.0 (5.9) 5	7.1 (3.5) 7	4.6 (2.9) 4	8.1 (3.5) 8	25.9 (8.5) 26
t- test		0.862	2.481	1.674	1.333	2.478
P		0.931	0.015	0.098	0.187	0.016
Gingival condition *						
Healthy gum 0	28 (37.3)	6.1 (3.1) 5.5	6.8 (4.2) 6.5	3.9 (2.7) 3	7.9 (3.7) 7.5	24.7 (10.4) 25
Unhealthy gum 1	47 (62.7)	5.8 (3.1) 5	6.9 (3.1) 7	4.9 (3.1) 5	7.9 (3.3) 7	25.5 (7.3) 26
t- test		0.380	0.060	1.463	0.017	0.391
P		0.705	0.952	0.148	0.986	0.697
Trauma condition *						
No trauma 0	37 (49.3)	5.9 (2.6) 5	6.7 (3.8) 6	4.2 (2.4) 4	7.9 (3.5) 8	24.5 (8.1) 25
Trauma present 1	38 (50.7)	5.9 (3.4) 5	6.9 (3.2) 7	4.7 (3.4) 4	7.9 (3.4) 7	25.5 (8.5) 26
t- test		0.035	0.233	0.648	0.000	0.305
P		0.972	0.817	0.519	0.999	0.761
Erosion *						
No erosion 0	53 (70.7)	6.0 (2.9) 5	6.9 (3.6) 7	4.2 (2.8) 4	7.9 (3.5) 7	25.1 (9.0) 26
Erosion present 1	22 (29.3)	5.7 (3.2) 5	6.7 (3.3) 6.5	5.1 (3.3) 5	8.0 (3.2) 7	25.6 (7.5) 25
t- test		0.376	0.198	1.229	0.043	0.219
P		0.708	0.843	0.223	0.966	0.827
Opacities *						
No opacities 0	63 (84)	6.3 (3.1) 6	6.9 (3.5) 6	4.4 (2.9) 4	8.0 (3.5) 7	25.6 (8.7) 25
Opacities present	12 (16)	4.1 (2.2) 4	6.5 (3.6) 7.5	5.2 (2.8) 6	7.8 (3.2) 7	23.7 (7.7) 26
t- test		2.373	0.288	0.867	0.153	0.699
P		0.020	0.774	0.389	0.879	0.487

* Children may have had more than one clinical condition.

6. DISCUSSION

6.1. Methodological issues

This study was designed to assess the translation of the original English versions of CPQ8-10 and PPQ6-14 into Arabic and to evaluate the psychometric properties of the Arabic versions. The results were obtained by measuring the ability of the translated instruments to discriminate between subjects with different levels of perceived oral health and to evaluate differences in OHRQoL between populations. Multi-staged cross-cultural adaptation of the questionnaire to other languages was essential, as a measure of the reliability of the questionnaire construction.

The adaptation of the index was based on the competence of children in relation to intellectual, cognitive and linguistic progression, so the Arabic version of the CPQ8-10 differed from the original in terms of Likert-type scales of severity and frequency, but overall perception remain unchanged.

The equivalence of the Arabic versions of the CPQ8-10 and P-CPQ was established according to the criteria of Guillemin et al (1993). Semantic equivalence was achieved by translation and back-translation, which resulted in a stable version of the questionnaire. Idiomatic equivalence was accomplished by having the translation reviewed by two independent panels of experts and by parents and children. Experiential equivalence was established by a pretest of the questionnaire, while conceptual equivalence was achieved by conducting qualitative interviews.

Difficulties were experienced with some questions during translation. For example, a GP on the forward translation team mentioned problems with items 15 and 16, which referred respectively to the child having been ‘upset’ and feeling ‘frustrated’ in the last four weeks. A dentist on the forward translation team also questioned item 19 in the parent questionnaire, which referred to feeling ‘anxious and fearful’. These difficulties were resolved during the first committee meeting, when the four translators and the researcher shared views regarding the translation. The paediatric psychiatrist suggested that the researcher should provide children with synonyms of the words ‘upset’ and ‘frustrated’ such as ‘disappointed’ and ‘annoyed’ respectively.

The translation process worked very well. However, literal translation may not be adequate, as some authorities have suggested that discussion within bilingual teams be used to establish the best fit and the most culturally sensitive items (Guillemin et al, 1993; Striener and Norman, 1996). Another possible advantage of this study was that the translation team comprised health professionals and non-professionals, making them more likely to fully understand the lay persons in the target groups.

There is no ideal for data collection. However, self-completed questionnaires are better than face-to-face interviews when dealing with educated participants, as a high response rate (about 70%) can be obtained, provided that the questionnaires are easy and short and that the questions do not require a face-to-face interview (Carter Y and Thomas C, 1997). In addition, the questionnaire should take into account the mode of appearance and the aims of the survey.

The questionnaires used in this study covered personal information and the impact of oral health on quality of life. A pilot study was undertaken to test the validity of the questionnaire items and to ensure they were based on concepts familiar to the target group. Other issues which were taken into account included the appropriateness of the language used, acceptability and the length of the questionnaire.

As shown by several studies, the content and construct validity of the instrument were clearly established in the present study, although the questionnaire might have been better if it had been administered in interview form. However, most oral health-related questionnaires have a high degree of subjectivity, as oral health may have a different impact on quality of life for different people. The scores on these instruments were also associated with self-rated oral health conditions, so further research is needed to determine if the pattern remains when they are applied to other oral health conditions or treatments.

The study was conducted in a public hospital setting, so it would be useful to extend it to other settings such private or military hospitals, in order to discover whether the findings are sensitive to the setting.

One possible concern is that the simpler CPQ8-10 and PPQ6-14 were first administered to adult participants and may have made them aware of oral impacts. Therefore the order of administration may have affected the level of impact detected by the measures.

Generally, all hypotheses concerning the construct and criterion validity of the Arabic versions of CPQ8-10 and PPQ6-14 were confirmed. The instrument proved valid when used to discriminate between groups by clinical location: quality of life measures were better in the PHCC group than in the hospital and dental centre groups. Furthermore, discriminant validity tests were able to determine whether the extent of disease or clinical signs within community, hospital and dental centre groups would be associated with quality of life scores. In other words, children in community or primary health care groups had better quality of life scores than those in hospital or dental centre clinic groups.

Values of Cronbach's alpha were satisfactory for all scales with the exception of the emotional well being scale as judged by parents. Scores on this scale may not reflect a unitary scale. This may be because parents experience differently in judging their child's emotional state, thus some items may be easy for parents to judge whereas others are not suggesting two different types of items in the same scale. My research supports the proposal by Eiser and Morse (2001), that future research should acknowledge the separate and important perspectives of the parent and the child particularly in this domain.

Cronbach's alpha scores for both nationalities were also confirmed as exceeding 0.4 for the whole scale and subscales. Self-rating of oral health status and oral health concerns were associated with scores on the CPQ8-10, confirming its construct validity. The results of the study suggest that socioeconomic variables such as household income may influence the oral health-related quality of life outcomes and that linguistic and literacy impairment may affect the participants' responses to some items in the questionnaire format.

Global communication will be improved by strengthening the cross-cultural adaptation process. The advantages of cross-cultural adaptation are that

comparatively little time and money is consumed. A rigorous and multi-step method of cross-cultural adaptation will produce a better translation.

6.2. Discussion of limitations

The present study had some limitations which might be considered in future Child OHRQoL research. For instance, it had a cross-sectional design, attempting to measure OHRQoL at a specific time but not to establish causal relationships. In addition, it was based on a clinical dental site population, so its findings cannot be applied to the general population. Thus, the findings are not valid beyond the group for which they were obtained and cannot be extended to the child Saudi population.
One item in particular remained unclear even after extensive testing, which was translated as “named by perplexed titles” and was originally “teased”. This was a particularly difficult concept to translate for this group. It is possible that the translated item does not reflect the original intention of this item.

Test retest reliability was not assessed which is a limitation of the findings. This is a common problem in psychometric testing for measures of OHRQoL, largely for pragmatic reasons. Often such measures are tested in clinical settings where individuals have attended for treatment. The assessment of test-retest reliability requires a steady state against which to judge the responses which is unethical to maintain in clinical populations.

The data from clinical measures should be interpreted with caution since there was delay between the examiner being calibrated (2005) and the study taking place (2008). Furthermore there was no assessment of intra-examiner repeatability because of limited time and difficulties in rebooking the children for the second appointment because most were on holiday when we recruited to the study. However all assessments were undertaken by a single examiner, so any bias would have operated across all groups.

Marshman and Hall (2008) argue for the greater involvement of children in determining the content and methods of research related to them. This study did not make wide use of child participation and involvement, future work should address this. This study was limited to 75 children aged between 8 and 10 years old of age,

which was chosen to parallel the original validation and development study for CPQ 8-10 by Jokovic et al (2004).

Also it was not possible to clinically examine the children in the UK as the candidate has only temporary registration with GDC in the UK. This limited the ability to compare data across countries.

As the design was cross-sectional, it is difficult to draw any conclusions about causality, so further longitudinal studies are needed in order to understand and interpret OHRQoL measures in children, although these would be difficult to conduct in developing countries because of poor population records and financial resources.

6.3. Relation to work reported in the literature

The study found that the overall scale and subscale scores for the two nationalities (Saudi and British) were nearly identical, with no significant differences among children or parents, except on the subscale of social wellbeing in the child questionnaire.

The reliability statistics were similar to those reported in the development of the original questionnaire (Jokovic et al, 2003; Jokovic et al, 2004). Relatively similar results were also reported for the Chinese version (McGrath et al, 2008), Spanish (Mexican) version (Del Carmen and Irigoyen, 2011), Persian version (Jabarifar et al, 2011) and Brazilian versions (Barbosa et al, 2009; Martins et al, 2009; Goursand et al, 2009).

Generally, comparing these results with those of other studies is problematic, because divergences may be due to differences in sample size and surroundings, but it appears that the scores obtained in the present study were considerably greater than those reported by European and American studies. This may be because of differences in culture or because the children in Europe and America have easy access to dental treatment, whereas most of our sample in Saudi Arabia had difficulty in accessing dental care.

A high variation was found in this study in the scores of the CPQ8-10 and P-CPQ6-14 and domains, most probably the result of the relatively small sample size and the degree of variation in clinical status amongst participants. Future research using this measure will require much larger and more homogenous groups of participants.

6.4. Future research

Future research should address a further exploration of the psychometric properties of the new scale in larger populations. This could take the form of additional data collection to address those properties not explored in this thesis, notably test-retest reliability, the factor structure of the scale, and how this relates to both the theoretical structure and other empirical tests of factorial validity. Finally the prevalence of items and the psychometric properties of the scale in non-clinical populations should be determined.

The assessment of the emotional well being of the child by parents had a low level of internal consistency in this study. This is not a unique finding and there is some suggestion from the published literature that parents may have difficulty in assessing their child's emotional well being. In terms of future research there may be a need for qualitative work to explore those aspects of the child's emotional well being which parents would feel they could rate, for example the behavioural components such as being tearful, social withdrawal, etc rather than asking parents to makes judgements on the child's internal world. In contrast the emotional well being scale for children can focus more on the child's internal states and feelings. This may increase the reliability of the scale, though we might hypothesise that focussing on behaviour may lose some of the more subtle aspects of emotional well being. Such qualitative work could be conducted with both parents and with experts in child psychology and behaviour, such as child psychologists, teachers of primary school and paediatric dentists.

The scale devised here can and should be used in large scales epidemiological studies for monitoring the health of the nation and defining need. Such studies should be both cross-sectional and longitudinal. Gherunpong et al (2004) have outlined how clinical data and quality of life data can be combined in determining the need for

dental services amongst populations. The creation of a Saudi version of the CPQ in this age group will allow this method to be adopted.

Further research in a broader range of locations is needed to support our study. Studies directed towards other specific conditions, such as the impact of orthodontic needs on quality of life, would also supplement work on dental lesions such as caries and opacities. It is important when assessing oral health dimensions and conceptions of oral health that the quality of life measure is as short as possible, consisting of a minimum number of items. This would allow the concept to be captured effectively while minimizing the burden on study participants and the cost of data collection and analysis.

Further research on larger samples and with longer follow-up would improve understanding of how the psychological factors relate to OHRQoL. Finally, future research should evaluate the relationship between oral health-related quality of life and general health, in order to advance the conceptual integration of oral health into general health. Finally the CPQ8-10 Saudi version will allow researchers to evaluate the impact of novel interventions, be they new methods of service delivery or new treatment approaches, on oral health related quality of life.

6.5 Policy implications

- Determining need for oral health services in Saudi Arabia.
- Exploration of the impact of policy changes on OHRQoL.
- Long term monitoring of the oral health of the population.
- The Arabic version of CPQ8-10 and PPQ6-14 developed in this study can be used to assess the effectiveness of dental interventions and oral health promotion programmes.
- The Arabic versions of CPQ8-10 and PPQ6-14 developed in this study may be useful in paediatric dentistry in other Arab countries.
- The findings of this study may have implications for the promotion of dental health education to children aged 8-10 years and their parents in Saudi Arabia in order to improve their quality of life.

6.6. Recommendations

- More evaluative studies should be undertaken by using OHRQoL measures as outcomes in different populations with a range of oral conditions in different setting.
- These versions were used in epidemiological cross-sectional and interventional studies, but it is most important to be able to assess the dental care needs of the population, so the measurement of treatment needs based on subjective indicators becomes essential for planning oral health services and assessing the costs of future dental care services.
- A comprehensive assessment of child oral health is useful to oral healthcare policy-makers for planning oral health care programmes in order to promote oral health resources and address oral health needs and demands. This should focus on oral health education, improving knowledge of the prospective treatment opportunities and provision of such services.
- The measurement of treatment needs based on subjective indicators is essential for the strategic planning of oral and dental health services, taking cost into account.
- General dental practitioners and paediatric dentists working elsewhere in Saudi Arabia or in other Arab countries will be able to use the Arabic versions of the questionnaires developed for this study, to assess the impact of oral health on the quality of life of their patients.
- The CPQ8-10 and PPQ6-14 scores were significantly associated with self-evaluation of oral health. A study in a clinical setting should ask the child about self-rated oral health and satisfaction with oral health, so it may be appropriate to use these two self-rated questionnaires rather than a more complex questionnaire.

6.7. Conclusions

- The Arabic version of the COHRQoL translated for this study showed acceptable validity and reliability in a dental clinic-based population.
- The Arabic versions developed for this study can be used for assessing OHRQoL in children aged 8-10 and their parents in Arab countries.
- From the findings of the first stage, it can be concluded that the Arabic versions of the CPQ8-10 and PPC6-14 seem to give valid and reliable measures of oral health-related quality of life in children 8-10 years old and their parents respectively.
- The Arabic versions of CPQ8-10 and PPQ6-14 developed for this study yielded almost identical psychometric results to those obtained from the English versions.
- The associations of OHRQoL in this study were found to be similar in children and their parents.
- The highest impact of OHRQoL was principally in the subscales relating to social and emotional wellbeing.
- A prospective study with a large sample is recommended in order to assess changes in oral health status and OHRQoL over time. It would also help to measure treatment outcomes and evaluate strategies and programmes to improve oral health.
- The results of this study suggest that the Arabic version of CPQ8-10 is a valid instrument for measuring OHRQoL in children, although it is limited to discriminating between children with dental caries, erosion, trauma and dental anomalies.
- The results of the present study support the current view that the Arabic versions of CPQ8-10 and PPQ6-14 provide important tools for international research, as they are cross-culturally valid and reliable.
- Children in Saudi Arabia score higher on social well being than the UK sample, indicating greater social impact than the UK samples. This indicates either true differences in social impact or a lack of equivalence in the translated version of the scale. While the translation appears to be largely equivalent it may overestimate social impact of oral conditions.

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APPENDICES

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Appendix 1: Ethical approval for Saudi sites (Arabic version)

المملكة العربية السعودية
وزارة الصحة
مديرية الشؤون الصحية بمحافظة الأحساء

وزارة الصحة
Ministry of Health

الرقم ٦٦-٧٩٨١٧/ ٤١/٥
التاريخ : ٢/ ١٢/ ١٤٢٨هـ
المرفقات : ١ لفه

عاجل جداً ويرسل اليوم

عبدالرؤف حسين الغدير ط/ أسنان سعودي

سعادة/ م. مدير الشئون الصحية للرعاية الأولية المحترم
سعادة/ مدير مستشفى الملك فهد بالهفوف المحترم
سعادة/ مديرة مركز طب الاسنان المحترمه

السلام عليكم ورحمة الله وبركاته ،،،

بطيه صورة خطاب مشرف خدمات طب الاسنان برقم ٢١٧٦٦ في ١٤٢٨/١٢/١هـ والمتضمن الموافقة على طلب المذكور أعلاه لأجراء دراسة تهدف إلى معرفة مدى تأثير صحةالفم والاسنان على صعيد الحياة اليومية بالنسبة للاطفال ما بين الثامنة والعاشرة وكذلك تأثيرها على الوالدين وذلك لاكمال البحث لديكم كمطلب للحصول على الشهادة واكمال الدراسة.

عليه نفيدكم بموافقة مدير الشئون الصحية على ذلك .

للاطلاع واكمال اللازم كالمتبع.

مع أطيب تحياتي ،،،

مدير إدارة التخطيط والتطوير الإداري

عبد العزيز بن عبد الرحمن العمير

صوره/ مع الاساس للتدريب (العمران)

التخطيط/ سعيد

الأحساء - الهفوف - هاتف ٥٧٥٥٤٢١ - ٥٧٥٤١١٤ - فاكس ٥٧٥٧٥١٠ - ٥٧٥٢٥٢٣ - تلكس KFUHS9 ٦٨١١٠٧

Appendix 2: Ethical approval for the Saudi sites (Translated version)

Kingdom of Saudi Arabia
Ministry of Health

Directorate Health Affairs in Al-Hasa Governorate (DHAAG)

Dr A H Alghadeer — **No. 21766/29/26/41**
Postgraduate student — **Date: 02/12/1428 H**
King's College London — **12/12/2007 G**

Cross cultural adaptation of the Child Oral Health Related Quality of Life measure in Al-Hasa, Saudi Arabia

Dear Primary Health Care Supervisor in Alhasa Sectors (PHCC)
Dear Director King Fahad Hospital Hofuf (KFHH)
Dear Director of Dental Centre in Alhasa (DC)

According to the letter from Managing Planning and Development Department manager No. 21766 dated 01/12/1428H (11/12/2007) based on the reference memorandum of Director of Health Affairs in Al-Hasa Governorate , enclosing the approval of the above mentioned named to carry his research collecting data from all three location of Dental Clinics (DC, KFHH and PHCC).

The decision was approved according to the letter from his Department at King's College London, signed by his supervisor Professor J T Newton, that the research will be a part of his studies that he will be conducting interviews with children and parents concerning the impact of their mouth, teeth and gums on their life, administering questionnaires and clinical examination of children. The first part of the study will consist of interviews; the second part will combine a questionnaire survey and a clinical survey.

Decision of the committee in the DHAAG

1. Agreeing for **Dr A H Alghadeer** to carry his scientific research to collect the necessary information for his research.
2. The original copy of the decision will be sent to Directorate Health Affairs in Al-Hasa Governorate. Thanks and regards
3. Any future adverse events, progress of trail regarding the study should be referred to the DHAAG.

Dr Mohammed Al-Bahrani
Director of Dental Services in Al-Hasa

Signature

Abdul-Aziz Al-Omair
Planning and Improvement Director

Signature

Al-Hasa – Al-Hofuf – Tel. 5755421 – 5754114 – Fax 5757510 – 5752523 – Telex 681107 KFUHS9

Appendix 3: Consent Form for the Saudi sites (Arabic version)

تأثير صحة فم وأسنان الطفل بين سن الثامنة والعاشرة على جودة الحياة اليومية على الطفل نفسه ووالديه في منطقة الإحساء بالمملكة العربية السعودية.

إسم القائم على البحث: عبدالرؤف الغدير

الرجاء وضع إشارة (√) للتأكيد

- **لقد قرأت ورقة المعلومات حول الدراسة.** **( )**
- **القائم على هذه الدراسة قد شرح لي محتوى الدراسة و أجاب على أسئلتي.** **( )**
- **أتفهم بأن مشاركتي في هذه الدراسة طوعية ولي حق الانسحاب في أي وقت.** **( )**
- **أتفهم بأن رفضي للمشاركة أو الانسحاب لن يؤثر في علاجي أو رعايتي الطبية لاحقا.** **( )**
- **أتفهم بأن كل المعلومات المأخوذة في هذه الدراسة سيتم التعامل معها بسرية تامة ، وإن كل البيانات عني وعن طفلي سوف تُمسح في حال نشر هذه المعلومات.** **( )**
- **أنا وطفلي نوافق على المشاركة في هذه الدراسة.** **( )**

اسم والد/والدة الطفل .....

توقيع والد/والدة الطفل ..... التاريخ .....

اسم الشخص القائم على الاستبيان .....

توقيع القائم على هذه الاستبيان ..... التاريخ .....

Appendix 4: Consent Form for the Saudi sites (Translated version)

Cross cultural adaptation of the Child Oral Health Related Quality of Life measure

	Please initial to confirm
• I have read the information sheet about the study.	( )
• The study representative has explained the study to me and has answered all of the questions I have at this time.	( )
• I understand that my participation is voluntary and I am free to withdraw at any time	( )
• I understand that refusing to participate or later withdrawing from the study will not adversely affect my subsequent medical or dental care.	( )
• I understand that all information collected in the study will be held confidentially and if it is presented or published all details of my child and me will be removed.	( )
• My child and I agree to take part in this study.	( )

Name of the child's parent……..

Signature of the child's parent……Date…….

Name of person taking consent……

Signature of person taking consent…….Date…….

Appendix 5: Information sheet for the Saudi sites (Arabic version)

معلومات للوالدين حول الدراسة

تأثير صحة فم وأسنان الطفل بين سن الثامنة والعاشرة على جودة الحياة اليومية على الطفل نفسه ووالديه في منطقة الإحساء بالمملكة العربية السعودية

السيد/السيدة ولي أمر الطفل/الطفلة ،

اسمي عبدالرؤوف الغدير وأنا طالب دراسات عليا بكلية كنجس كولج بجامعة لندن بالمملكة المتحدة. وإنني حاليا أقوم بمشروع دراسة حول تأثير صحة فم وأسنان الطفل بين سن الثامنة والعاشرة على جودة الحياة اليومية على الطفل نفسه ووالديه في منطقة الإحساء.

تهدف هذه الدراسة إلى تقييم تأثير صحة فم وأسنان الطفل بين سن الثامنة والعاشرة على جودة الحياة اليومية على الطفل نفسه ووالديه في منطقة الإحساء.

لذا نرجو منكم التكرم بالمشاركة في هذه الدراسة أثناء زيارتكم للعلاج. تتضمن هذه الدراسة فحص سريع لأسنان طفلكم بالاضافة إلى بعض الأسئلة المتعلقة بكم وبطفلكم. ويستغرق ذلك حوالي 20 دقيقة من وقتكم.

عزيزي ولي الأمر، لن تؤثر هذه الدراسة بأي حال من الأحوال على مستوى الرعاية الصحية المقدمة لكم ولطفلكم ، هذا بالإضافة إلى أن لديكم الحق في عدم المشاركة أو الانسحاب من الدراسة متى ما رغبتم في ذلك، بدون إبداء أي سبب.

إذا كانت لديكم استفسارات أو تحتاجون إلى معلومات إضافية، فلا تتردد في ذلك.

في حالة موافقتكم على المشاركة في هذه الدراسة ، نرجو منكم التكرم بالتوقيع على استمارة الإقرار المرفقة.

شكرا جزيلا لتعاونكم معنا.

المخلص لكم ،

عبدالرؤوف الغدير

Appendix 6: Information sheet for the Saudi sites (Translate version)

Cross cultural adaptation of the Child Oral Health Related Quality of Life measure

Dear parent

My name is Abdulraof Alghadeer and I am a Postgraduate dentist studying at the King's College London in the United Kingdom. I am carrying out a research project relating to the Child Oral Health Related Quality of Life.

Child Oral Health Related Quality of Life has an impact on the everyday life and values activities of children and their parents.

The purposes of my research study to assess and determined the prevalence and impact of oral health on everyday life on children aged 8- 10 years and their parents in Alhasa, Saudi Arabia.

The interview and the examination will take about 20 minutes.

Taking part in the study will not affect your right to any treatment quality of care in the health centre. You also may withdraw at any point during the examination and interview without giving a reason and without affect your future care.

If you have any questions or you need any further information please ask?
If you agree to participate in the study please sign the consent form.
Thank you very much for your attention and co-oparation,

Yours sincerely,
Abdulraof Alghadeer

Appendix 7 : Parent questionnaire for the Saudi sites (Arabic version)

استبيان عن تأثير صحة فم وأسنان الطفل بين سن الثامنة والعاشرة على جودة الحياة اليومية

استبيان للوالدين أو المرافق

نشكركم على موافقتكم للمشاركة في هذه الدراسة. اسمي عبد الرؤف الغدير طالب دراسات عليا في جامعة لندن بالمملكة المتحدة. الهدف من هذه الدراسة هو إعطاؤنا فكرة عن تأثير الوضع الصحي لفم وأسنان الطفل مابين سن الثامنة والعاشرة في منطقة الأحساء. لذا نرجو منكم التكرم بالإجابة على الأسئلة التالية المتعلقة بالموضوع علما بأن كل الإجابات سيتم التعامل معها بسرية تامة.

تعليمات للوالدين:

1. هذا الاستبيان يوضح تأثير حالة صحة فم وأسنان الطفل على جودة الحياة اليومية وحياة أسرهم وذلك بأي حالة مرتبطة بالأسنان أو الشفتين أو الفم والفكين، الرجاء الإجابة على جميع الأسئلة.
2. ضع علامة (✓) أمام الإجابة المناسبة.
3. الرجاء عدم مناقشة هذه الأسئلة مع طفلك لأننا نريد معرفتها بواسطة طريق الوالدين أو المرافق فقط.
4. اختر الإجابة الأقرب والتي تصف حالة طفلك، وإذا كان السؤال لا يتناسب مع حالة طفلك فأجب بـ (أبدا).

مثال على ذلك: كم مرة شعر طفلك بصعوبة في التركيز في الفصل الدراسي؟

مثلا إذا كان طفلك لا يستطيع طفلك التركيز في الفصل بسبب مشكلة في أسنانه أو فمه أختر الإجابة المناسبة، أما إذا كان عدم التركيز بسبب آخر أجب بـ (أبدا)

أبدا☐ مرة أو مرتين ☐ أحيانا ☐ كثيرا ☐ كل يوم ☐ لا أعلم ☐

أولاً: معلومات عن الطفل

- العيـــــــــــــادة: _____
- جنس الطفل: • _____ العمر: _____•
- قام بالإجابـــة:• الأم☐ الأب☐ شخص آخر(حدد) ☐ _____
- التاريـــــــــــخ: يوم _____ شهر _____ سنة _____

ثانياً: أسئلة عن صحة فم وأسنان الطفل

	ممتازة	جيدة جداً	جيدة	لا بأس	سيئة
1. كيف تقيم صحة فم وأسنان وشفتين وفكين طفلك؟					

	أبداً	قليلا جداً	نوعاً ما	كثيراً	كثيراً جداً
2. هل تتأثر سعادة طفلك بسبب مشكلة في أسنانه وشفتيه وفكيه وفمه؟					

ثالثاً: أسئلة عن مدى تأثير راحة الطفل بسبب مشكلة في أسنانه أو فمه أو فكيه

خلال الثلاثة أشهر الماضية، وبسبب مشكلة في أسنانه أو شفتيه أو فمه أو فكيه، كم مرة تعرض طفلك لما يلي:

	أبداً	مرة أو مرتين	أحياناً	كثيراً	كل يوم	لا أعلم
3. ألم في أسنانه أو شفتيه أو فكيه أو فمه؟						
4. نزيف في اللثة؟						
5. قرحة في الفم؟						
6. رائحة كريهة؟						
7. طعام عالق في سقف الفم؟						
8. طعام ملتصق بين الأسنان؟						
9. صعوبة في مضغ بعض الأطعمة كالتفاح أو الذرة أو اللحم؟						
10. تنفس عن طريق الفم؟						
11. صعوبة في النوم؟						
12. صعوبة في نطق بعض الكلمات؟						
13. وقت أطول في الأكل؟						
14. صعوبة في شرب أو أكل الأطعمة الباردة أو الساخنة؟						
15. صعوبة في أكل طعام يرغب في أكله؟						
16. اقتصر على تناول بعض أنواع الأطعمة؟ (مثلاً: الأطعمة اللينة)						

رابعاً: أسئلة عن تأثير حالة أسنان وشفتين وفم وفكين الطفل وتأثيره على حالته النفسية أو أنشطته اليومية

خلال الثلاثة أشهر الماضية، وبسبب مشكلة في أسنانه أو شفتيه أو فمه أو فكيه، كم مرة تعرض طفلك لما يلي:

	أبداً	مرة أو مرتين	أحياناً	كثيراً	كل يوم	لا أعلم
17. إزعاج أو اضطراب؟						
18. عصبية أو إحباط؟						
19. قلق أو خوف؟						
20. تغيب عن المدرسة بسبب موعد أو ألم أو عملية جراحية في الفم أو الأسنان؟						
21. صعوبة في التركيز أثناء الحصة الدراسية؟						
22. لا يريد التحدث أو القراءة بصوت عالي في المدرسة؟						
23. لا يريد التحدث مع أطفال آخرين؟						
24. يتجنب الابتسامة أو الضحك مع أطفال آخرين؟						
25. أصبحت قلق بأن صحته أقل من صحة غيره؟						
26. قلق بأنه مختلف عن الأطفال الآخرين؟						
27. شعور بأن الآخرين أجمل منه؟						
28. تصرف بخجل أو بارتباك؟						
29. ينادونه بعض الأطفال بألقاب غير محببة؟						
30. ابتعاد بعض أطفال عنه؟						
31. لا يريد الجلوس مع أطفال آخرين؟						
32. لا يريد المشاركة في الأنشطة العامة كالرياضة أو الرحلات والمناسبات العامة كالأعياد؟						
33. قلق لقلة أصدقائه؟						
34. يهتم بما يقوله الناس عن أسنانه أو شفتيه أو فمه أو فكيه؟						
35. سأله أطفال آخرون عن أسنانه أو شفتيه أو فمه أو فكيه؟						

خامساً: أسئلة عن حالة فم الطفل ومدى تأثيرها على والديه أو أحد أفراد أسرته

خلال الثلاثة أشهر الماضية، وبسبب مشكلة في أسنانه أو شفتيه أو فمه أو فكيه، كم مرة تعرضت أو أحد أفراد الأسرة لمايلي:

	أبداً	مرة أو مرتين	أحياناً	كثيراً	كل يوم	لا أعلم
36. أصبح مضطرباً؟						
37. أصبح نومه غير منتظم؟						
38. شعور بالذنب؟						
39. تغيب عن العمل بسبب ألم أو موعد أو عملية جراحية في الأسنان؟						
40. أصبح لديه وقت أقل لنفسه و عائلته؟						
41. أصبح قلقاً بأن الطفل سيصبح لديه فرص أقل من غيره في الحياة كفرص العمل أو الزواج؟						
42. شعور بعدم الراحة في الأماكن العامة كالأسواق أو المنتزهات مع الطفل؟						
43. الغيرة منك أو من أحد أفراد الأسرة؟						
44. توبيخ منك أو من أحد أفراد الأسرة؟						
45. مناقشة معك أو مع أحد أفراد الأسرة؟						
46. اهتمام أكثر منك أو من أحد أفراد الأسرة؟						
47. تعارض مع بعض المناسبات العائلية؟						
48. نشوء خلاف أو عدم اتفاق بين أفراد الأسرة؟						
49. صعوبات مالية للأسرة؟						

Appendix 8: Child questionnaire for the Saudi sites (Arabic version)

استبيان عن تأثير صحة فم وأسنان الطفل بين سن الثامنة والعاشرة على جودة الحياة اليومية

أ. استبيان خاص بالطفل

نشكركم على موافقتكم للمشاركة في هذه الدراسة. اسمي عبد الرؤف الغدير طالب دراسات عليا في جامعة لندن بالمملكة المتحدة. الهدف من هذه الدراسة هو إعطاؤنا فكرة عن الوضع الصحي لفم وأسنان الطفل مابين سن الثامنة والعاشرة في منطقة الأحساء ومدى تأثيرها على الحياة اليومية على الطفل ووالديه. لذا نرجو منكم التكرم بالإجابة على الأسئلة التالية المتعلقة بالموضوع علما بأن كل الإجابات سيتم التعامل معها بسرية تامة.

ي:

1. الرجاء عدم كتابة الاسم على النموذج
2. هذا ليس اختبار ولا توجد إجابة صحيحة أو خاطئة
3. أجب بصدق بقدر المستطاع
4. لا تطلب المساعدة من أي شخص
5. لن يطلع أي شخص على إجاباتك
6. أقرأ الأسئلة بتمعن وأجب عنها من خلال ما حدث لك في الأربعة أسابيع الماضية
7. اسأل نفسك قبل أن تجيب هل هذه الأشياء حصلت بسبب مشكلة في أسنانك أو فمك
8. ضع علامة (✓) أمام الإجابة المناسبة

أولاً: بعض الأسئلة الشخصية عن نفسك

1. **هل أنت ذكر أو أنثى؟** ☐ ذكر ☐ أنثى

2. **متى ولدت ؟** يوم ___ شهر ___ سنة ___ العمر: _____

3. **ما رأيك بالحالة الصحية لأسنانك وفمك؟ الرجاء اختيار الوصف المناسب:**
   سيئة☐ لا بأس ☐ جيدة ☐ جيدة جدا ☐

4. **هل تتضايق من حالة أسنانك أو فمك الصحية في حياتك اليومية؟**
   كثيراً☐ أحياناً ☐ قليلاً ☐ أبداً ☐

ثانياً: بعض الأسئلة عن أسنانك وفمك

خلال الأربعة أسابيع الماضية، وبسبب مشكلة في أسنانك أو فمك أو فكيك، كم مرة تعرضت لما يلي:

	ولا مرة	مرة أو مرتين	أحياناً	كثيراً	كل يوم أو أكثر الأيام
5. ألم في أسنانك أو فمك؟					
6. بقع مؤلمة في فمك؟ 					
7. ألم في أسنانك بسبب تناول شراب حار أو بارد؟					
8. طعام ملتصق في أسنانك؟					
9. رائحة كريهة؟					
10 وقت أطول لتناول الطعام؟					
11. صعوبة عند مضغ الطعام كالتفاح أو الذرة؟ 					
12. امتنعت عن تناول طعام ترغب في أكله؟					
13. صعوبة في نطق بعض الكلمات؟					
14. صعوبة في النوم؟ 					

ثالثاً: بعض الأسئلة عن شعور الطفل

خلال الأربعة أسابيع الماضية، وبسبب مشكلة في أسنانك أو فمك أو فكيك، كم مرة تعرضت لما يلي:

	ولا مرة	مرة أو مرتين	أحياناً	كثيراً	كل يوم أو أكثر الأيام
15. اضطراب؟ 					
16. إحباط؟					
17. خجل؟					
18. اهتمام برأي الآخرين؟					
19. شعرت بأن مظهرك غير محبب؟					

رابعاً: بعض الأسئلة عن الحالة الدراسية

خلال الأربعة أسابيع الماضية، وبسبب مشكلة في أسنانك أو فمك أو فكيك، كم مرة تعرضت لما يلي:

	ولا مرة	مرة أو مرتين	أحياناً	كثيراً	كل يوم أو أكثر الأيام
20. تغيبت عن المدرسة؟ 					
21. صعوبة في أداء واجباتك المدرسية؟					
22. لا تستطيع التركيز خلال الحصة الدراسية؟ 					

	ولا مرة	مرة أو مرتين	أحياناً	كثيراً	كل يوم أو أكثر الأيام
23. لا تريد التكلم أو تقرأ بصوت عالي؟					

خامساً: بعض الأسئلة عن علاقتك بالآخرين

خلال الأربعة أسابيع الماضية، وبسبب مشكلة في أسنانك أو فمك أو فكيك، كم مرة تعرضت لما يلي:

	ولا مرة	مرة أو مرتين	أحياناً	كثيراً	كل يوم أو أكثر الأيام
24. تتجنب الضحك أو الابتسامة مع أطفال آخرين؟					
25. لا تريد التحدث مع أطفال آخرين؟					
26. لا تريد اللعب مع أطفال آخرين؟ 					
27. لا تريد المشاركة في أنشطة جماعية مع أطفال آخرين؟ 					
28. ضايقك أطفال آخرون بألقاب غير محببة إليك؟					
29. سألك أطفال آخرون عن أسنانك أو فمك؟					

انتهت الأسئلة

Appendix 9 : Parent questionnaire for the Saudi sites (Back translation)

A Questionnaire about Child oral health related quality of life

Parental report (6-14 years)

B. Parents Questionnaire

Parents Instructions:

1. This questionnaire shows the effect of children's mouth and teeth health on children and their families on everyday life.
2. Tick (✓) the appropriate answer.
3. Please don't discuss these questions with your child.
4. Choose the best answer which describes your child condition. If the question is not related to your child condition, please choose (never).

E.g. How often did your child have difficulty in concentration in his/her classroom because of a problem in his mouth or teeth? Choose the appropriate answer. But if lack of concentration was caused by another reason, then choose (never).

☐ I don't know ☐ Everyday ☐ A lot ☐ sometimes ☐ Once or twice ☐ never

First: Child Information

1. Child gender: ☐ Male ☐ Female

2. His/her age: _____ years

3. This questionnaire is answered by:

☐ Mother ☐ Father ☐ Another person (specify) _____

4. Date: Day _____ Month _____ Year _____

Second: questions about the child's mouth and teeth health

	Poor	Fair	Good	Very good	Excellent
1. How do you evaluate your child teeth, lips jaws, and mouth health?					

	Very much	A lot	Some	Very little	Not at all
2. How is your child generally wellbeing affected by the condition of his/her teeth, lips, jaws, and mouth?					

Third: questions ask about the effect of the child comfort because of the condition of their teeth, mouth, or jaws

During the last three months, because of a problem in his/her teeth, mouth, or jaws, how often did your child have the following?

	I don't know	Everyday	Often	Sometimes	Once or twice	Never
3. Pain in his/her teeth, lips, or jaws?						
4. Gum bleeding?						
5. Mouth ulcer?						
6. Bad breath?						
7. Stuck food in the floor of his/her mouth?						
8. Stuck food between his/her teeth?						
9. Difficulty in chewing some food such as apple, corn, or meet?						
10. Mouth breathing?						
11. Sleeping difficulty?						
12. Difficulty in pronouncing some words?						
13. Taking more time in eating?						
14. Difficulty in eating or drinking cold or hot food?						
15. Difficulty in eating that he/she prefers?						
16. Eating only some kind of food such as soft food?						

Fourth: The following questions ask about the effects of the condition child's teeth, lips, jaws, and mouth on his/her psychological status and everyday activities

During the last three months, because of a problem in his/her teeth, lips, mouth, or jaws, how often did your child have the following?

	I don't know	Everyday	Often	Sometimes	Once or twice	Never
17. Upset or anxiety?						
18. Depression or nervousness?						
19. Worries or fear?						
20. Absence from school because of an appointment, pain, or a surgery in his/her mouth or teeth?						
21. Difficulty in concentration in the school?						
22. Did not want to speak or read loudly in the school?						
23 did not want to talk to other children?						
24. Avoided to smile or laugh with other children?						
25. Became less healthy than other children?						
26. Worried that he/she is different from other children?						
27. Felt that the others are more beautiful than him?						
28. Acted shamefully or embarrassed?						
29. Called mocking names?						
30. Refused by other children?						
31. Did not want to set with other children?						
32. Did not want to participate in the activities such as sports, trips, public celebrations?						
33. Worried because he/she has few friends?						

34. Care for what people said about his/her mouth, jaws, lips, or teeth?						
35. Asked by other children about his/her teeth, mouth, lips, or jaws?						

Fifth: The following questions about effects of the child mouth condition may have on his parents or one of his family members

During the last three months, because of a problem in his/her teeth, lips, or mouth, how often did you or one of the family members have the following?

	I don't know	Everyday	Often	Sometimes	Once or twice	Never
36. Upset?						
37. Irregular sleeping?						
38. Guilty?						
39. Absence from work because of pain, an appointment, or surgery in teeth?						
40. Less time for him/her on his/her family?						
41. Worried because the child will have less opportunity than the other in work life?						
42. Uncomfortable feeling in public utilities such as markets and parks?						
43. Jealousy of you or one of the family members?						
44. Blamed by you or one of the family members?						
45. Discussion with you or one of the family members?						
47. Confliction with a family occasion?						
48. Disagreement between the families?						
49. Financial difficulties in the family?						

Appendix 10: Child questionnaire for the Saudi sites (Back translation)

A Questionnaire about the child oral Health (8-10 years)

A. Child Questionnaire

Please remember:

1. Don't write your name.
2. This is not an exam. So, there is no right or wrong answer.
3. Answer as honestly as possible.
4. Don't ask for help from anyone.
5. Nobody you know will see your answers.
6. Read the questions carefully, and answer them by remembering what happened to you throughout the last four weeks.
7. Ask yourself before you answer wither these things happened because of your teeth or mouth.
8. Tick (✓) in the appropriate answer.

First: Some Personal Questions about Yourself

1. Gender: ☐ Boy ☐ Girl

2. Your birthday: day _____ month _____ year _____
Age_____

3. What do you think about health condition of your teeth and mouth? Choose the appropriate description:

☐ Very good ☐ good ☐ O.K ☐ Poor

4. How much do your teeth or mouth trouble your health in every day life?

☐ Not at all ☐ A little bit ☐ Sometimes ☐ A lot

Second: Some questions about your teeth and mouth

During the last four weeks, because of a problem in your teeth, mouth, or jaws, how often have you had the following?

Questions	answers

	Never	Once or twice	Sometimes	Often	Daily or almost everyday
5. Pain in your mouth or teeth?					
6. Painful spots in your mouth?					
7. Pain in your teeth because of hot or cold drink?					
8. Stuck food in your teeth?					
9. Bad breath?					
10. Need more time to eat?					
11. Difficulty in chewing some food such as apple or corn?					
12. Refuse to eat preferred food?					
13. Difficulty in pronouncing some words?					
14. Difficulty in sleeping?					

Third: some questions about your feeling

During the last four weeks, because of a problem in your teeth, mouth, or jaws, how often have you had the following?

	Never	Once or twice	Sometimes	Often	Daily or almost everyday
15. Feel upset?					
16. Feel frustrated?					
17. Been ashamed?					
18. Been concerned what other people think about your teeth or mouth?					
19. Worried that you are not have good appearance?					

Fourth: some questions about you school

During the last four weeks, because of a problem in your teeth, mouth, or jaws, how often have you had the following?

	Never	Once or twice	Sometimes	Often	Daily or almost everyday
20. Absent from school?					
21. had difficulty doing your homework?					
22. Could not concentrate in classroom?					
23. don't want to speak or read loudly?					

Fifth: some questions about your relation with others

During the last four weeks, because of a problem in your teeth, mouth, or jaws, how often have you had the following?

	Never	Once or twice	Sometimes	Often	Daily or almost everyday
24. Avoid laughing or smiling with other children?					
25. Avoid speaking with other children?					
26. Avoid playing with other children?					
27. Avoid participating in groups activities with other children?					
28. Called mocking names?					
29. Asked by other children about your teeth or mouth?					

Appendix 11: Transcript of the qualitative interviews

Cross cultural adaptation of the Child Oral Health Related Quality of Life measure

Focus group discussion transcripts of Qualitative Interviews:

Four interviews were conducted in all three Dental Clinic, one in King Fahad Hospital Hofuf, Al-Hasa Dental Centre and in Primary Health Care. Each interview take about 30 minuets.

R: Researcher.
P1: Participant 1, Father of a child boy 10 years old interview in King Fahad Hospital Hofuf.
P2: Participant 2, father of a child boy 8 years old were interview at Al-Hasa Dental Centre.
P3: Participant 3, mother of a child girl 8 years old were interview at Primary Health Care Centre (Alfaisaleya).

A. King Fahad Hospital Interview:

R: First of all, thank you very much for agreeing to do this interview. I really appreciate it. The aim of this study is to help us to gain a better understanding of oral health related quality of life in children aged 8-10 years. Also we are interested in locking the Parental Perception of Child Oral Health-related Quality of Life. So this interview will take about 20-30 minutes, is that ok, for you.
P1: Ok, that's fine.
R: What do you think about the impact of oral diseases in every day life?
P1: It is very important.
R: So what are the most important domains that impacts in you and your child life?
P1: A lot.
R: Can you give me some example?
P1: Yes, such as time consuming, missing woks and school and sleeping disturb.
R: Now, I will give you a two copy of the questionnaire, one related to your child the other one related to you.
P1: Ok... no problem.

R: First, this is the questionnaire related to the child ; please follow me while I am asking you about your opinion, please look in the first section what do you think is it clear for the child?

P1: About the q2 the child can't remember the date of birth, however he will till you his age.

R: Ok, would you please look to the part two in the questionnaire, what do you think is it clear for the child, do you think any thing missing in this section?

P1: Generally it is clear, however q6 need explanation for the child.

R: Oh, Ok, would you please look to the section three? What do you think about these questions?

P1: All the questions in this section need explanation especially q15 and q16.

R: Ok, do you think we need to add any other questions in this part?

P1: No, it is more enough.

R: Ok, would you please read section four about the effect of dental problems in the child school.

P1: All questions are clear, although q23is not essential.

R: Ok, would you please look to the last section in the questionnaire, section six, about being children with other children?

P1: I think it is understandable but the q26 and q27 same questions.

R: Thank you very much, now I will give you the other part of the questionnaire about the Parental Perception of Child Oral Health-related Quality of Life.

P1: Ok, that's fine.

R: Would you please look for the second section in the page 2, is the question clear?

P1: Yes, it clear and understandable.

R: Ok, what about section three?

P1: Generally, all questions are clear and understandable but some of them not possible to know if my child have this symptoms or discomfort?

R: Can you give an example of these questions?

P1: Yes, such as q7 and q10.

R: Ok, in this case you can select (Don't Know) answer.

P1: Oh yes.

R: Would please read section four and five and give me your opinion.

P1: Ok, give me five minuets.

R: Sure.

P1: Again all the questions are clear except q38 and q43, I think it is not making any sense.

R: Finally, do you have any other comment or any missing questions?

P1: Mm…No, I have no thing to add.

R: That's all, Thank you. Thank you very much for your patient and your time.

B. Dental Centre Interview:

R: First of all, thank you very much for agreeing to do this interview. I really appreciate it. The aim of this study is to help us to gain a better understanding of oral health related quality of life in children aged 8-10 years. Also we are interested in locking the Parental Perception of Child Oral Health-related Quality of Life. So this interview will spend about 20-30 minutes, is that ok, for you.

P2: No problem

R: What do you think about the impacts of oral diseases in every day life?

P2: It is an important part.

R: So what are the most important domains that impacts in you and your child life in relation to Oral Health Related Quality of Life?

P2: Many

R: Can you give me some them?

P2: Yes, such as missing business and school, in addition some times missing pray time.

R: What do you mean about missing pray time?

P2: I mean some times due to dental appointment I can't pray on time.

R: Aha…Now, I will show you the two copy of the questionnaire, one related to the child and the other related to the parent.

P2: That's fine, no problem.

R: First, this is the child copy; please read with me while I am asking you about your opinion, please look in the first section what do you think is it clear for the child?

P2: In my opinion it is clear except q4, I think it needs more explanation for the child.

R: Ok, what about section two?

P2: That's fine, no problem.

R: What do you think about sections three and four please?

P2: Mm…regarding section three it is very difficult to understand by the child it self particularly q15, q16 and q17, which need to clarify the words and use more local words.

R: What about section four?

P2: That one clear and reasonable.

R: What do you think about section five please?

P2: This section very clear and much easier to understand than other sections.

R: Now can I discuss with you the other questionnaire if you have time?

P2: How long it takes?

R: about 15 minuets.

P2: Ok, that's fine.

R: Many thanks…this is the section related to the Parental Perceptions of Child Oral Health-related Quality of Life. Would you please read second and third section in page No. 2, and give your opinion?

P2: Generally, all the questions clear, but some of these questions are difficult to give our view.

R: Like what?

P2: Such as q8.

R: Any how in this case you can choose the answer (I don't know).

P2: Oh, that's fine.

R: Can you read section four on page No. 3 and tell me about the understandable and clarity?

P2: Yes, give me some times.

R: Ok.

P2: Clear and easy to understand meaning.

R: Can you check section five please?

P2: No problem, all clear and make sense except q43 which not making any sense.

R: Finally, would you please tell me in general do we need to add any questions.

P2: No, that enough.

R: That's all, Thank you. Thank you very much for your patient and your time.

P2: Ok, you thank you as well. Bye.

C. Primary Health Care Interview:

R: First of all, thank you very much for coming today for this interview. I really appreciate it. The aim of this study is to help us to gain a better understanding of oral health related quality of life in children aged 8-10 years. Also we are interested in

locking the Parental Perception of Child Oral Health-related Quality of Life. So this interview will take about 20-30 minutes, is that ok, for you.

P3: It's Ok.

R: What do you think about the impacts of oral diseases in every day life?

P3: It is an essential measurement.

R: So what are the most common domains that impacts in every day life to you and your child in relation to Oral Health Related Quality of Life?

P3: Many things

R: Can till me about that, I mean can give an example?

P3: Yes, such as sleeping disturb, missing time and cost many.

R: See…now, I will give you the two copy of the questionnaire, one related to the child and the other related to the parent.

P3: Why?

R: In order to discuss with you about the form and content of the questions and take your opinions?

P3: Aha…ok…no problem.

R: First, this is the child copy; please read with me while I am asking you about your opinion, please look in the first section what do you think is it clear for the child?

P3: It is difficult to understand without explanation especially q4.

R: Ok…how we can do explanation.

P3: By reading the question with child and give him some example.

R: Ok…what about section two in page No.2?

P3: Please give me some times.

R: Ok…take your time.

P3: I think, it is clear for the child age 10 years old, but it is difficult to understand by child age 8 or 9 years old.

R: So. What we can do to overcome this problem?

P3: Again read it with child and explain for him.

R: Now. What do you think about section three and four in the page No. 3?

P3 Same before….need explanation particularly section three which is difficult to understand without explanation.

R: Ok dear can you look at section four and give me your opinion.

P3: It is clearer than the other section. However some children may need to provide him more explanation.

R: Ok..what do you think do we need to add more items?

P3: No need…it more enough for the child.

R: Now I will read with you the questionnaire related to the parent.

P3: Ok.

R: Would you please read section two and three in page No. 2?

P3: Ok, give me some time.

R: Fine.

P3: See. In my opinion all the questions are clear for the parent, but q7 and q8 are difficult to make sure about the answer.

R: O.k. in this case parent can choose the answer (I don't Know).

P3: Aha.

R: What about section four and five?

P3: All the questions are clear but some of the questions no making any sense.

R: Can till which questions please?

P3: Yes, such as q 38, q43 and q45.

R: Finally, do we need to add more items or questions?

P3: No.

R: That's all, Thank you. Thank you very much for your patient and your time.

P3: O.k. pleasure.

Appendix 12: Parent Questionnaire for the English sites

CHILD ORAL HEALTH QUESTIONNAIRE

Parental report

6-14 years

INSTRUCTIONS TO PARENTS

1. This questionnaire is about the effects of oral conditions on children's wellbeing and everyday life, and the effects on their families. We are interested in any condition that involves teeth, lips, mouth or jaws. **Please answer each question**.

2. To answer the question please put an ☒ **in the box by the response**.

3. Please give the response that **best describes your child's experience**. If the question does not apply to your child, please answer with "Never".

Example: How often has your child had a hard time paying attention in school?

If your child has had a hard time paying attention in school because of problems with his/her teeth, lips, mouth or jaws, choose the appropriate response. If it has happened for other reasons, choose "Never".

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

5. Please **do not discuss the questions with your child,** as we are interested only in the parents' perspective in this questionnaire.

SECTION 1: Child's oral health and wellbeing

1. How would you rate the health of your child's teeth, lips, jaws and mouth?

❑ Excellent ❑ Very good ❑ Good ❑ Fair ❑ Poor

2. How much is your child's overall wellbeing affected by the condition of his/her teeth, lips, jaws or mouth?

❑ Not at all ❑ Very little ❑ Some ❑ A lot ❑ Very much

SECTION 2: The following questions ask about symptoms and discomfort that children may experience due to the condition of their teeth, lips, mouth and jaws

During the last 3 months, how often has your child had:

3. Pain in the teeth, lips, jaws or mouth?

❑ Never ❑ Once or twice ❑ Sometimes ❑ Often ❑ Every day or almost every day ❑ Don't know

4. Bleeding gums?

❑ Never ❑ Once or twice ❑ Sometimes ❑ Often ❑ Everyday or almost everyday ❑ Don't know

5. Sores in the mouth?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

6. Bad breath?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

7. Food stuck in the roof of the mouth?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

8. Food caught in or between the teeth?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

9. Difficulty biting or chewing foods such as fresh apple, corn on the cob or firm meat?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

During the last 3 months, because of his/her teeth, lips, mouth, or jaws, how often has your child:

10. Breathed through the mouth?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

11. Had trouble sleeping?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

12. Had difficulty saying any words?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

13. Taken longer than others to eat a meal?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

14. Had difficulty drinking or eating hot or cold foods?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

15. Had difficulty eating foods he/she would like to eat?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

16. Had diet restricted to certain types of food (e.g. soft food)?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

SECTION 3: The following questions ask about the effects that the condition of children's teeth, lips, mouth and jaws may have on their feelings and everyday activities

During the last 3 months, because of his/her teeth, lips, mouth or jaws, how often has your child been:

17. Upset?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

18. Irritable or frustrated?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

19. Anxious or fearful?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

During the last 3 months, because of his/her teeth, lips, mouth or jaws, how often has your child:

20. Missed school (e.g. pain, appointments, surgery)?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

21. Had a hard time paying attention in school?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

22. Not wanted to speak or read out loud in class?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

23. Not wanted to talk to other children?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

24. Avoided smiling or laughing when around other children?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

During the last 3 months, because of his/her teeth, lips, mouth or jaws, how often has your child:

25. Worried that he/she is not as healthy as other people?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

26. Worried that he/she is different than other people?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

27. Worried that he/she is not as good-looking as other people?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

28. Acted shy or embarrassed?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

29. Been teased or called names by other children?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

30. Been left out by other children?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

31. Not wanted or been unable to spend time with other children?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

32. Not wanted or been unable to participate in activities such as sports, clubs, drama, music, school trips?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

33. Worried that he/she has fewer friends?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

During the <u>last 3 months</u>, how often has your child been:

34. Concerned what other people think about his/her teeth, lips, mouth or jaws?

□	.	□	.	□	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

35. Asked other children about his/her teeth, lips, mouth or jaws?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

SECTION 4: The following questions ask about effects that a <u>child's oral condition</u> may have on <u>PARENTS AND OTHER FAMILY MEMBERS</u>

During the <u>last 3 months</u>, because of your child's <u>teeth, lips, mouth or jaws</u>, how often have you or another family member:

36. Been upset?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

37. Had sleep disrupted?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

38. Felt guilty?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

39. Taken time off work (e.g. pain, appointments, surgery)?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

40. Had less time for yourself or the family?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

41. Worried that your child will have fewer life opportunities (e.g. for dating, getting married, having children, getting a job he/she will like)?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

42. Felt uncomfortable in public places (e.g. stores, restaurants) with your child?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

During the last 3 months, because of his/her teeth, lips, mouth, or jaws, how often has your child:

43. Been jealous of you or others in the family?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

44. Blamed you or another person in the family?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

45. Argued with you or others in the family?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

46. Required more attention from you or others in the family?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

During the last 3 months, how often has the condition of your child's teeth, lips, mouth or jaws:

47. Interfered with family activities at home or elsewhere?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

48. Caused disagreement or conflict in your family?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

49. Caused financial difficulties for your family?

❑	❑	❑	❑	❑	❑
Never	Once or twice	Sometimes	Often	Everyday or almost everyday	Don't know

SECTION 5: Child's gender and age

a. Your child is:

- ❑ MALE
- ❑ FEMALE

b. Your child's age is: _____YEARS

Questionnaire completed by:

- ❑ MOTHER
- ❑ FATHER
- ❑ OTHER_____

c. **Householder income:**

1. less than £ 15,000
2. more than £ 20,000 to £ 23,000
3. more than £ 23,000 to £ 30.000
4. more than £ 30,000 to £ 52,000
5. more than £ 52,000

THANK YOU FOR YOUR PARTICIPATION !

Appendix 13: Child Oral health Questionnaire 8-10 for the English site study

CHILD ORAL HEALTH QUESTIONNAIRE

8-10 years

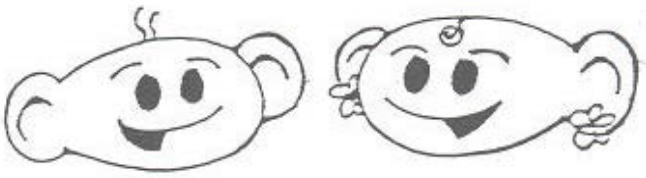
Hello,

Thanks for helping us with our study!

We are doing this study to understand better things that may happen to children because of their **teeth and mouth**.

PLEASE REMEMBER:

- Don't write your name on the questionnaire.
- This is **not a test** and there are no right or wrong answers.
- Answer as **honestly** as you can.
- **Don't talk to anyone** about the questions when you are answering them.
- **No one** you know will see your answers.
- Read each question **carefully** and think about the things that have happened to you in the **past 4 weeks**.
- Before you answer, ask yourself**: "Does this happen to me because of my teeth or mouth?"**
  Put an □ in the box beside the answer that is **best** for you.



FIRST, A FEW QUESTIONS ABOUT YOU

Today's date: _____/_____/_____
DAY MONTH YEAR

1. Are you a boy or a girl?

Boy
Girl

2. When were you born? _____/_____/_____ **Age** _____
DAY MONTH YEAR

3. When you think about your teeth or mouth, would you say that they are:

Very good
Good
O.K.
Poor

4. How much do your teeth or mouth bother you in your everyday life?

Not at all
A little bit
Some
A lot

NOW A FEW QUESTIONS ABOUT YOUR TEETH AND MOUTH

How often have you had:

5. Pain in your teeth or mouth in the past 4 weeks?

Never
Once or twice
Sometimes
Often
Everyday or almost every day

6. Sore spots in your mouth in the past 4 weeks?

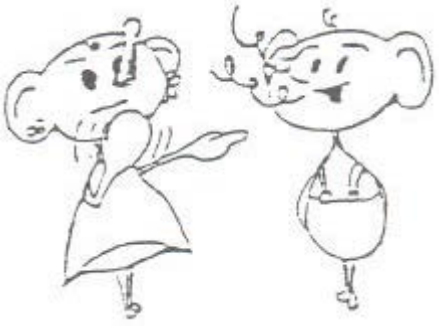
Never
Once or twice
Sometimes
Often
Everyday or almost every day

7. Pain in your teeth when you drink cold drinks or eat hot foods in the past 4 weeks?

Never
Once or twice
Sometimes
Often
Everyday or almost every day

8. Food stuck in your teeth in the past 4 weeks?

Never
Once or twice
Sometimes
Often
Everyday or almost every day



9. Bad breath in the past 4 weeks?

Never
Once or twice
Sometimes
Often
Everyday or almost every day

How often have you:

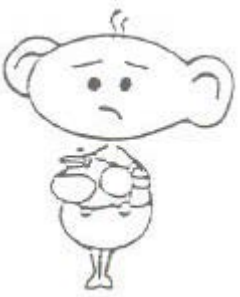
10. Needed longer time than others to eat your meal because of your teeth or mouth in the past 4 weeks?

Never
Once or twice
Sometimes
Often
Everyday or almost every day

11. Had a hard time biting or chewing food like apples, corn on the cob or steak because of your teeth or mouth in the past 4 weeks?

Never
Once or twice
Sometimes
Often
Everyday or almost every day

12. Had trouble eating foods you would like to eat because of your the past 4 weeks?

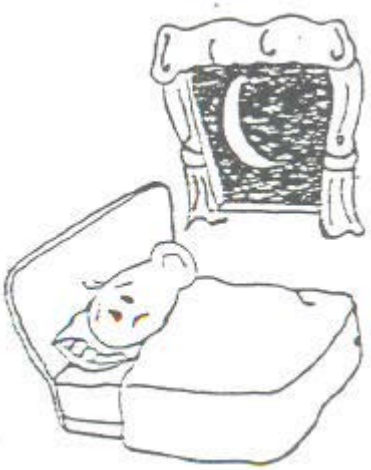


Never
Once or twice
Sometimes
Often
Everyday or almost every day

13. Had trouble saying some words because of your teeth or mouth in the past 4 weeks?

Never
Once or twice
Sometimes
Often
Everyday or almost every day

14. Had a problem sleeping at night because of your teeth or m in the past 4 weeks?



Never
Once or twice
Sometimes
Often
Everyday or almost every day

SOME QUESTIONS ABOUT YOUR FEELINGS

How often have you:

15. Been upset because of your teeth or mouth in the past 4 weeks?

Never
Once or twice
Sometimes
Often
Everyday or almost every day

16. Felt frustrated because of your teeth or mouth in the past 4 weeks?

Never
Once or twice
Sometimes
Often
Everyday or almost every day

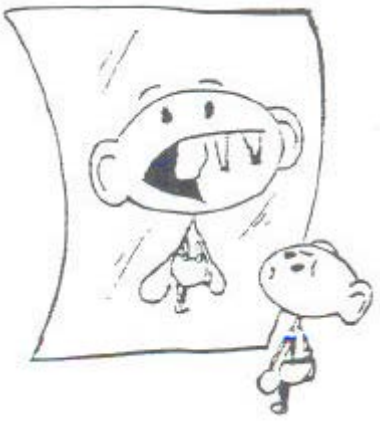
17. Been shy because of your teeth or mouth in the past 4 weeks?

Never
Once or twice
Sometimes
Often
Everyday or almost every day

18. Been concerned what other people think about your teeth or mouth in the past 4 weeks?

Never
Once or twice
Sometimes
Often
Everyday or almost every day

19. Worried that you are not as good-looking as others becaus your teeth or mouth in the past 4 weeks?



Never
Once or twice
Sometimes
Often
Everyday or almost every day

QUESTIONS ABOUT YOUR SCHOOL

How often have you:

20. Missed school because of your teeth or mouth in the past 4 we

Never
Once or twice
Sometimes
Often
Everyday or almost every day

21. Had a hard time doing your homework because of your teeth or mouth in the past 4 weeks?

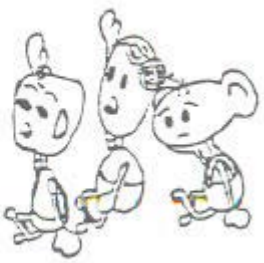
Never
Once or twice
Sometimes
Often
Everyday or almost every day

22. Had a hard time paying attention in school because of your teeth or mouth in the past 4 weeks?

Never
Once or twice
Sometimes
Often
Everyday or almost every day

23. Not wanted to speak or read out loud in class because of your teeth or mouth in the past 4 weeks?

Never
Once or twice
Sometimes
Often
Everyday or almost every day

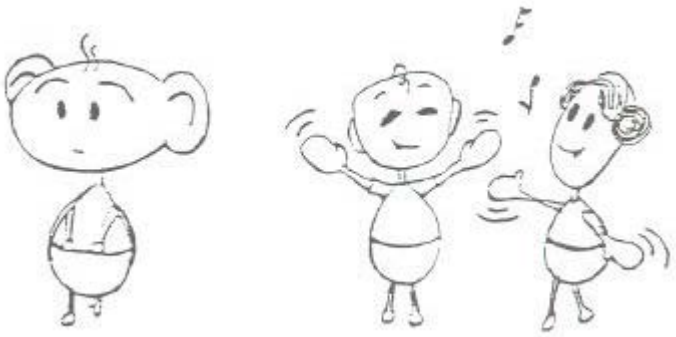


QUESTIONS ABOUT YOU BEING WITH OTHER PEOPLE

How often have you:

24. Tried not to smile or laugh when with other children because of your teeth or mouth in the past 4 weeks?

Never
Once or twice
Sometimes
Often
Everyday or almost every day



25. Not wanted to talk to other childr because of your teeth or mouth in past 4 weeks?

Never
Once or twice
Sometimes
Often
Everyday or almost every day

26. Not wanted to be with other children because of your teeth or mouth in the past 4 weeks?

Never
Once or twice
Sometimes
Often
Everyday or almost every day

27. Stayed away from activities like sports and clubs because of your teeth or mouth in the past 4 weeks?

Never
Once or twice
Sometimes
Often
Everyday or almost every

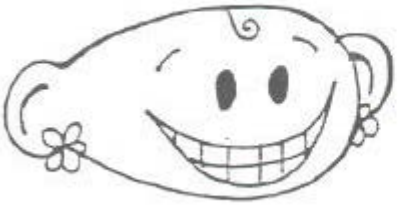
How often have:

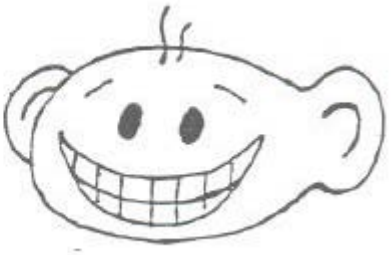
28. Other children teased you or called you na
the past 4 weeks?

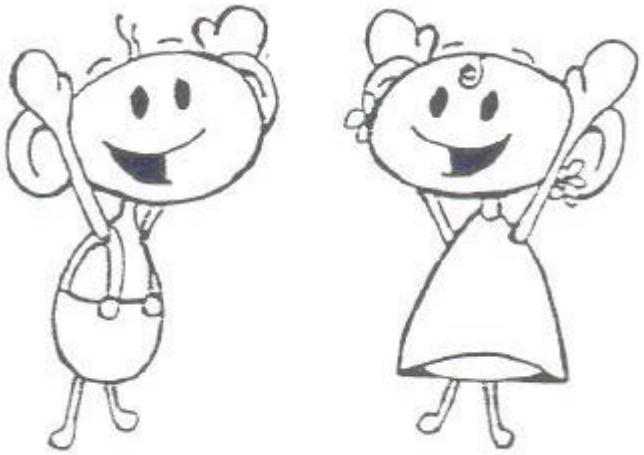
Never
Once or twice
Sometimes
Often
Everyday or almost every day

29. Other children asked you questions about your teeth or mouth in the past 4 weeks?

Never
Once or twice
Sometimes
Often
Everyday or almost every day







THANK YOU FOR YOUR HELP

Appendix 14: Clinical records for Saudi sites

Area number: | | | **/** **Patient number** | | | |

Cross cultural adaptation of a Child Oral Health Related Quality of Life measure

Name of the centre:……. **Name of the area:……..**

Name of the child: ……

Date of birth:……. **Gender: (0) male (1) female**

Charting for dental caries :

Right side **Left side**

6	**e**	**d**	**c**	**2**	**1**	**upper**	**1**	**2**	**c**	**d**	**e**	**6**
						D						
			xxxx	xxxx	xxxx	**O**	xxxx	xxxx	xxxx			
						M						
						B						
						L						
6	**e**	**d**	**c**	**2**	**1**	**lower**	**1**	**2**	**c**	**d**	**e**	**6**
						D						
			xxxx	xxxx	xxxx	**O**	xxxx	xxxx	xxxx			
						M						
						B						
						L						

CRITERIA OF TOOTH CONDITION

0	Sound	**8**	Unerupted
1	Decayed (arrested dentinal)	**R**	filling need replacement (not cariuos)
2	Decayed	**N**	Obvious sealant restoratin
3	Decayed with pulpal involvement	**$**	Sealant (type unknown)
4	Filled and decay	**T**	Trauma
5	Filled with no decay	**C**	Crown/advanced restorative procedure
6	Extracted due to caries	**9**	Excluded

Charting for gingival examination:

UPPER								
	Right			**Middle**			**Left**	
Gums	0	1	9	0	1	9	0	1	9
Plaque	0	1	9	0	1	9	0	1	9
Calculus	0	1	9	0	1	9	0	1	9
LOWER								
	Right			**Middle**			**Left**	
Gums	0	1	9	0	1	9	0	1	9
Plaque	0	1	9	0	1	9	0	1	9
Calculus	0	1	9	0	1	9	0	1	9

CRITERIA FOR GINGIVITIS

Gums	**Plaque**	**Calculus**
0 Healthy (no treatmeant)	**0** None visible	**0** No calculus
1 Not healthy	**1** Plaque visible	**1** Calculus present
9 Assessment cannot be made	**9** Assessment cannot be mad	**9** Assessment cannot be mad

Charting for trauma of the permanent incisor

	UPPER				**LOWER**			
	Right		**Left**		**Right**		**Left**	
2	**1**	**1**	**2**		**2**	**1**	**1**	**2**
0	0	0	0		0	0	0	0
1	1	1	1		1	1	1	1
2	2	2	2		2	2	2	2
3	3	3	3		3	3	3	3
4	4	4	4		4	4	4	4
5	5	5	5		5	5	5	5
6	6	6	6		6	6	6	6
7	7	7	7		7	7	7	7
8	8	8	8		8	8	8	8
9	9	9	9		9	9	9	9

CRITERIA FOR TRAUMA

0 No trauma
1 Discolouration
2 # Enamel
3 # Enamel and dentine
4 **#** Enamel, dentine and pulp
5 Missing due to trauma
6 Acid etch composite
7 Permanent replacement
8 Temporary restoration
9 Assessment cannot be made

Charting of erosion for maxillary incisor teeth:

Left			**Right**	
2	**1**		**1**	**2**

CRITERIA FOR DENTAL EROSION

0 Normal
1 Enamel only
2 Enamel and dentine
3 Enamel, dentine and pulp
9 Assessment cannot be made

Charting of enamel opacities for upper anterior teeth:

Left		**Right**
1		**1**

CRITERIA FOR DENTAL OPACITIES

0 Normal
1 Demarcated opacity
2 Diffuse opacity
3 Hypoplasia

Charting of oro-facial anomalies:

0 No abnormality ( )
1 Present ( )
Comments:……..

Appendix 15: Calibration result

Calibration for BASCD Co-ordinated Survey of 5 year olds 2005/06 West Yorkshire, North and East Yorkshire and North Lincolnshire and South Yorkshire

Dewsbury	Tooth Condition						
N=22	dft						
	dt	mt	ft	dmft	Sensitivity	Specificity	Kappa
Standard	1.68	0.09	0.32	2.09			
A (Keith)	1.68	0.09	0.45	2.23	0.90	0.99	0.85
B (Gill)	1.59	0.09	0.41	2.09	0.80	0.97	0.76
C (Stella)	1.77	0.05	0.32	2.14	0.76	0.95	0.68
D (Jini)	1.23	0.09	0.73	2.05	0.82	0.98	0.79
E (Liz)	1.77	0.09	0.73	2.59	1.98	0.76	0.81
F (Ian)	1.45	0.09	0.45	2.00	0.82	0.96	0.74
G (Paul)	1.32	0.05	0.59	1.95	0.92	0.98	0.85
H (Sean)	1.41	0.09	0.50	2.00	0.80	0.99	0.85
I (Abdulrauf)	1.95	0.09	0.23	2.27	0.93	0.97	0.84
J (Shahid)	1.09	0.09	0.45	1.64	0.73	0.99	0.79

Appendix 16: Ethical approval for the English sites

NHS
National Research Ethics Service
King's College Hospital Research Ethics Committee
Camberwell Building
King's College Hospital
94 Denmark Hill
London
SE5 9RS

Telephone: 0203 299 3923
Facsimile: 0203 299 5085

26 June 2009

Dr Abdulraof Alghadeer
PhD Student
King's College London
Oral Health Services Research & DPH
King's College Hospital
Caldecot Road, London
SE5 9RW

Dear Dr Alghadeer

Study Title: **Cross cultural adaptation of a Child Oral Health Related Quality of Life measure in children aged 8 to 10 years**

REC reference number: **09/H0808/62**
Protocol number:

The Research Ethics Committee reviewed the above application at the meeting held on 17 June 2009.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

1. **The Patient information Sheet needs to be clearer that this is a comparison and that it is being undertaken for a PhD.**
2. **The consent form mentions parent's dental records rather than child's dental records.**
3. **Version control is used on all documentation.**

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

09/H0808/62	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

Dr David Jewitt
Chair

Email: william.bowen@kch.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*
"After ethical review – guidance for researchers"

Copy to: *Mr Keith Brennan, King's College London*

King's College Hospital Research Ethics Committee

Attendance at Committee meeting on 17 June 2009

Dr David Jewitt, Chairman/ Consultant Cardiologist. **Dr Brian O'Connor, Vice Chair/Consultant in Respiratory Medicine** Ms Cathy Walton, Consultant Midwife. Dr Will Bernal, Consultant Liver Intensivist Prof John Garrett, Professor Emeritus Dr Patrick Gordon, Consultant Rheumatologist	Mr Kai-Loke Chan, Pharmacist Dr Colin Ball, Consultant Paediatrician John Fowler, Lay member. Dr Nora Donaldson, Statistician Rev David Rushton, Chaplain Ms Madeleine Colvin, Lay Member Dr Mike Philpot, Consultant in Old Age Psychiatry Dr Rebecca Cassidy, Lay Member

NHS
National Research Ethics Service

King's College Hospital Research Ethics Committee
Research Ethics Office
1st Floor Camberwell Building
King's College Hospital
Denmark Hill, London
SE5 9RS

Chair: Dr David Jewitt
Administrator: Will Bowen
Direct line: 020 3299 3923
Fax: 020 3299 5085

Email: William.bowen@kch.nhs.uk
Website: www.nres.npsa.nhs.uk

Dr Abdulraof Alghadeer
PhD Student
King's College London
Oral Health Services Research & DPH
King's College Hospital
Caldecot Road, London
SE5 9RW

29 July 2009

Dear Dr Alghadeer

Re: **Cross cultural adaptation of a Child Oral Health Related Quality of Life measure in children aged 8 to 10 years**
REC REF: **09/H0808/62**

Thank you for your correspondence dated 2 July 2009 enclosing The Patient Information Sheet and the Consent Forms for the above trial. It has been noted and placed on file.

Kings College Hospital is compliant with ICH GCP guidelines

Yours sincerely

Will Bowen
Research Ethics Committee Co-ordinator

Full Membership of the King's College Hospital Research Ethics Committee:

Dr David Jewitt, Chairman/ Consultant Cardiologist	Dr Brian O'Connor, Consultant, Respiratory Medicine
Dr Colin Ball, Paediatrician	Reverend David Rushton Chaplain
Dr Will Bernal, ICU Liver Consultant	Ms Catherine Walton, Consultant Midwife
Mr Kai Loke Chan Pharmacist	Dr Luke Zander, GP Member
Dr Nora Donaldson, Statistician	Ms Madeleine Colvin, Lay member
Prof John Garrett, Professor Emeritus, Oral Pathology	Mr John Fowler, Lay member
Mr Juan Gonzalez Statistician	Dr Mike Philpot Consultant, Old Age Psychiatry
Prof Sir Michael Rutter, Consultant, Child Psychiatry	Dr Rebecca Cassidy, Lay Member

This Research Ethics Committee is an advisory committee to London Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England

Appendix 17: Consent form for the English sites

King's College Hospital NHS
NHS Foundation Trust

KCL Dental Institute
Bessemer Road
London SE5 9RS

Tel: 020 3299 9000
Fax: 020 3299 3185
www.kch.nhs.uk

CONSENT FORM

(Version: 2.0 dated 01/07/2009)

Title of the Project: Cross cultural adaptation of a Child Oral Health Related Quality of Life measure

Name of Researcher: Abdulraof Alghadeer

		please initial box
1.	I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving reason and without my or my child's dental care or legal rights being affected.	
3.	I understand that sections of any of my child's dental notes may be looked at by responsible individuals from King's College London Dental Institute where it is relevant to my child's taking part in the study. I give permission for these individuals to have access to my child's dental records.	
4.	I agree to my child taking part in the above study.	

Name of the child	Date	signature
Name of the Parent/Guardian	Date	signature
Name of person taking consent (if different from researcher)	Date	signature
Researcher	Date	signature

Appendix 18: Information sheet for the English sites

King's College Hospital NHS
NHS Trust

Guy's, King's & St. Thomas' Dental Institute
Bessemer Road
London SE5 9RS

Tel: 020 7737 4000
Fax: 020 7346 3185

Information sheet for participants
(Version: 2.0 dated 01/07/2009)

Cross cultural adaptation of a Child Oral Health Related Quality of Life measure

You are being invited with your child to take part in a research study. This study has also been conducted in Saudi Arabia and the results of that study will be compared with the results from this study. Before you decide to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with the researcher if you wish. Ask us if there is anything that is not clear or if you would like more information. Thank you for reading this information sheet.

What is the purpose of this study?
The purpose of the study is to assess the impact of oral health of the children on the quality of life for the children it self and their parents. This study is part of my research for a PhD degree.

Why I have been chosen?
You have been invited to take part in the study because your child/guardian is aged between 8-10 years/old and we would like to study 75 children with their parent.

Do I have to take part?
It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdrawn at any time, or a decision not to take part, will not affect the standard of dental care for you and your child/guardian.

What will happen to me if I take part?
You and your child will be asked to complete the questionnaire related to impact of oral health related quality of life one for you and the other for your child. Completing questionnaire will last about 20 minutes.

What are the possible disadvantages and risks of taking part?
Only giving 20 minuets of your valuable time

What are the possible benefits of taking part?
We are assessing the impact of oral health related quality of life on your life and your child. This information we get from this study may help us to assess and improve some oral health programme.

Will my taking part in this study be kept confidential?
All information which is collected about you and your child will be kept strictly confidential. Any information about you and your child/guardian that recognise your name and your child will be removed.

What will happen to the results of the research?
The results may be publish in scientific journals or presented at conferences. You and your child/guardian will not be identified in any report or publication.

Who is organising and funding the research?
The research is based at King's College London Dental Institute, and is being funded by MOH of Saudi Arabia.

Who has reviewed the study?
The study has been reviewed by King's College Hospital research Ethics Committee.

Contact for further information?
If you would like further information about the study, please ask Abdulraof Alghadeer or contact Professor Tim Newton, Professor of Psychology as applied to Dentistry & Deputy Director of Research & Development, King's College Hospital Foundation NHS Trust. Department Oral Health Services Research & Dental Public Health, Caldecot Road, London SE5 9RW. Tel: 0203 299 3481. E mail: tim.newton@kcl.ac.uk

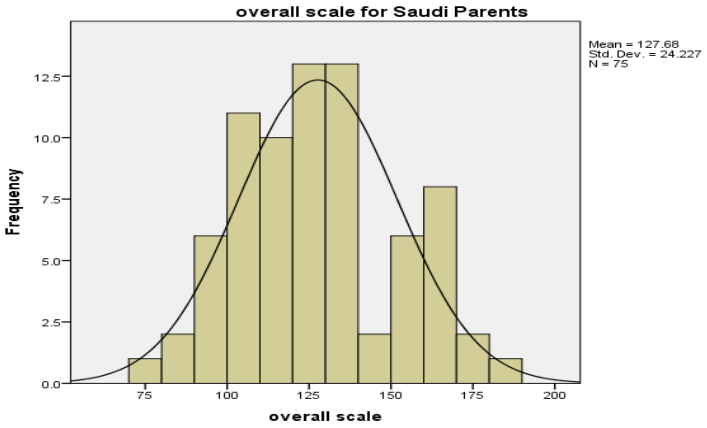
If you decide to take part in the study you will be given a copy of the information sheet and signed consent form to keep.

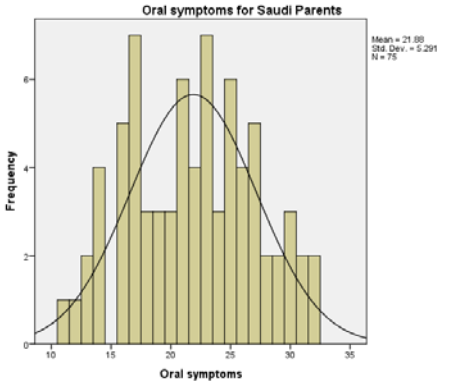
Thank you for considering taking part in this study.

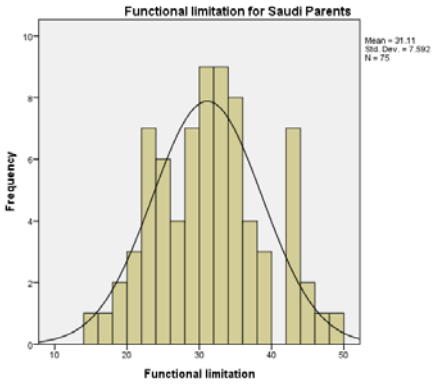
Appendix 19: Frequency distributions for overall scale and subscale variables in Saudi Arabia and the UK

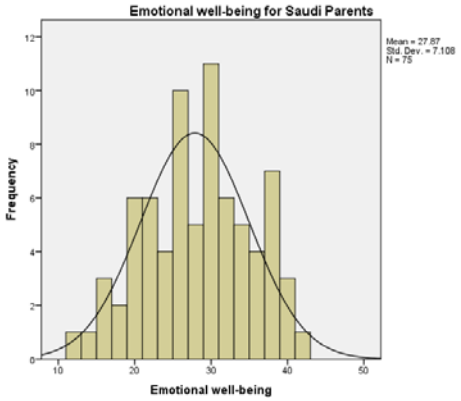
- **Appendix 19-A:** Frequency distributions for overall scale and subscale variables of Saudi Parents.
- **Appendix 19-B:** Frequency distributions for overall scale and subscale variables of Saudi child.
- **Appendix 19-C:** Frequency distributions for overall scale and subscale variables of UK child.
- **Appendix 19-D:** Frequency distributions for overall scale and subscale variables of the UK Parents.

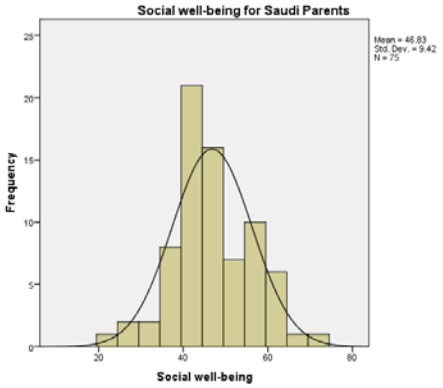
Appendix 19-A: Frequency distributions for overall scale and subscale variables of Saudi Parents.



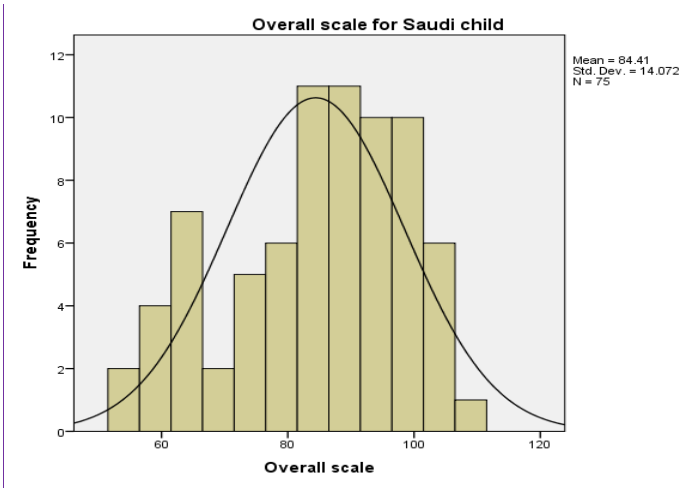


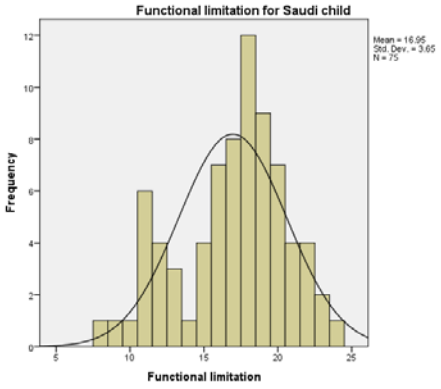


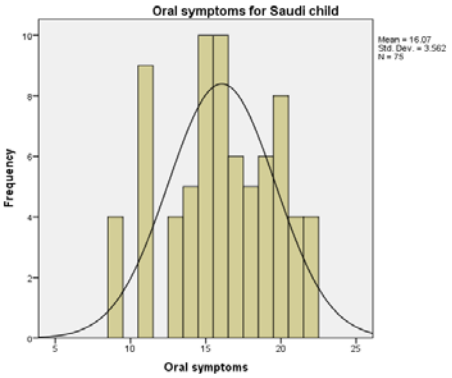


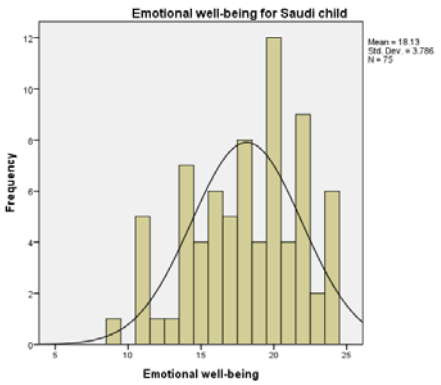


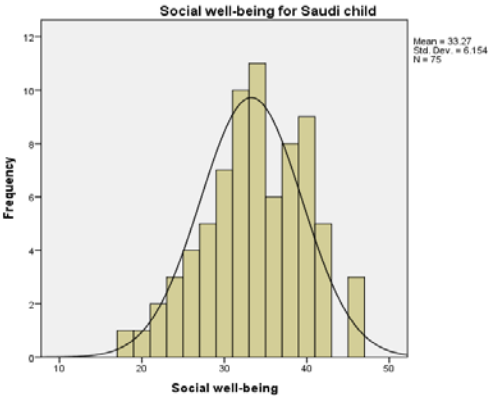
Appendix 19-B: Frequency distributions for overall scale and subscale variables of Saudi child.



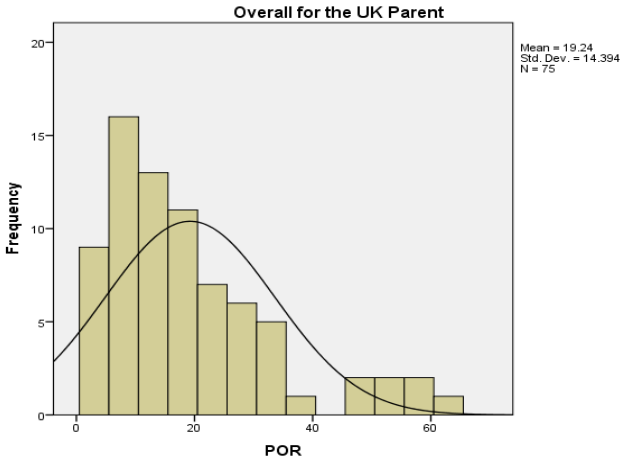


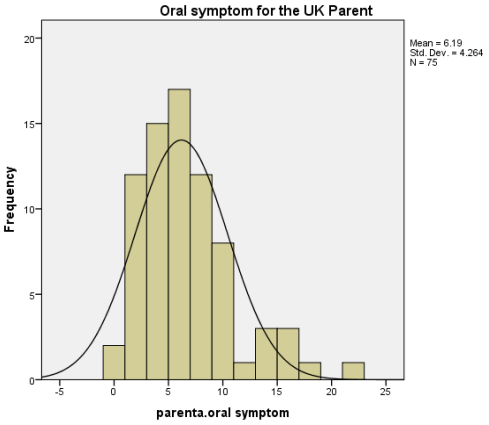


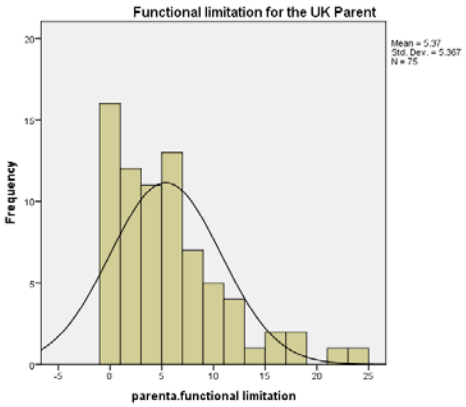


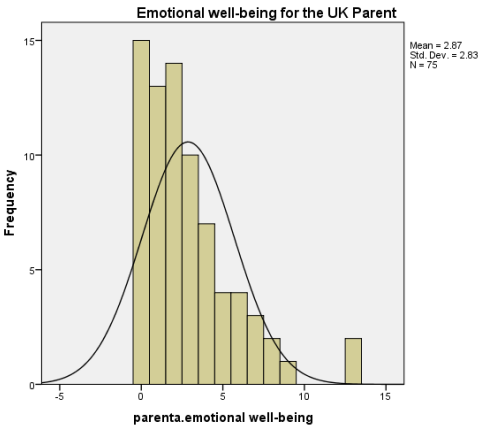


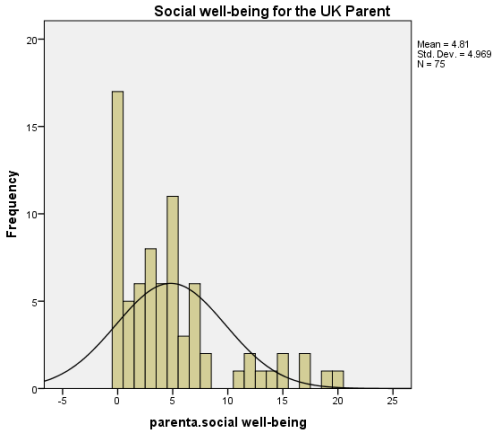
- **Appendix 19-C:** <u>Frequency distributions for overall scale and subscale variables of UK Parent.</u>



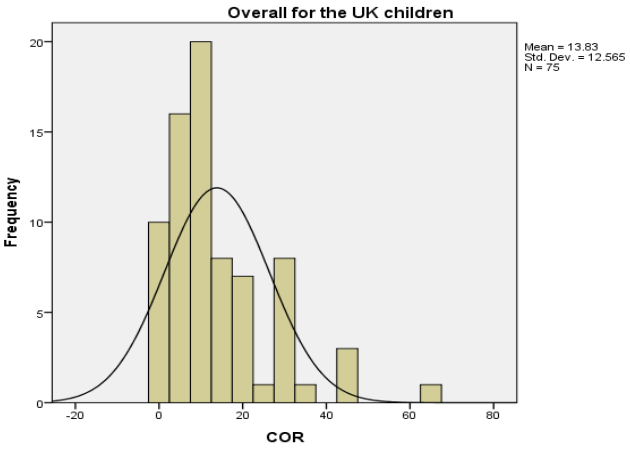


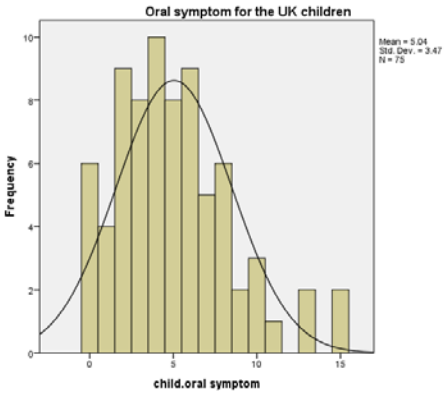


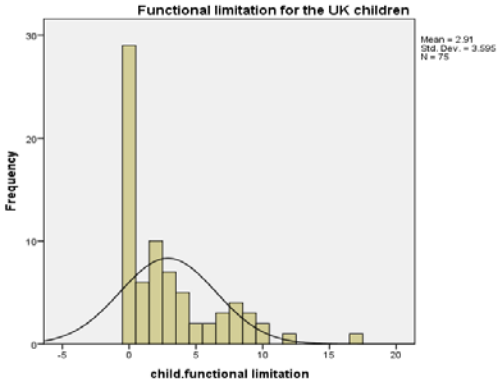


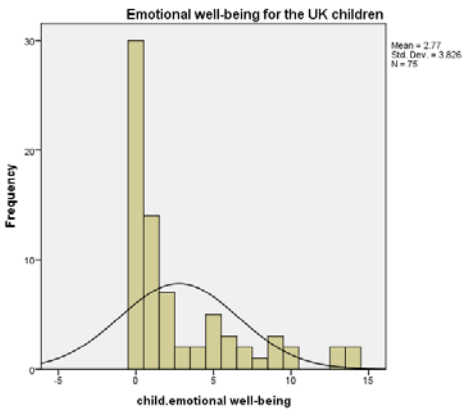


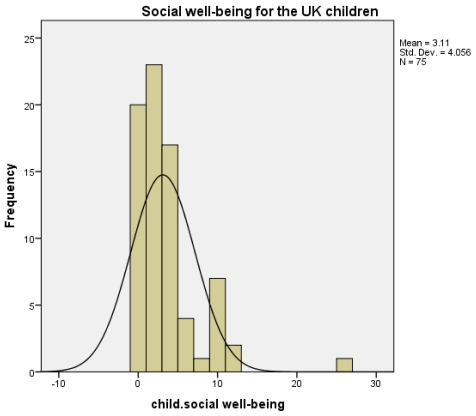
- **Appendix 19-D:** <u>Frequency distributions for overall scale and subscale variables of the UK Child.</u>











Appendix 20: Published Abstracts, Paper and conference Presentations Arising from this Thesis

- **Appendix 20-A:** Cross-cultural adaptation of Oral Health Related Quality of Life, Poster Presentation in **BSDR Conference**, Glasgow, Sept 1-4. 2009

- **Appendix 20-B:** OHRQoL in Children 8-10 in Saudi Arabia and England in **IADR 88th** General Session and Exhibition, Barcelona, Spain (July 14-17- 2010).

- **Appendix 20-C:** Development and Validation of Arabic version of CPQ8-10 in **IADR 89th** General Session and Exhibition, San Diego, USA (March 16-19- 2011).

- **Appendix 20-D:** Oral Health related Quality of Life in children aged 8-10 in Saudi Arabia and England in **BSDR**, Sheffield, UK (12-15 September 2011)

- **Appendix 20-E:** Cross Cultural Adaptation of Oral Health-Related Quality of Life Measures, Published in ***Dental Update*** Journal in December 2010; **37**: 706-708.

Appendix 20-A Cross-cultural adaptation of Oral Health Related Quality of Life, Poster Presentation in **BSDR Conference**, Glasgow, Sept 1-4. 2009

Cross cultural adaptation of Oral Health Related Quality of Life

A. ALGHADEER, King's College London, London, United Kingdom

Background and objectives: Oral Health Related Quality of Life (OHRQOL) is the shift in the perception of health from merely the absence of disease and infirmity to complete physical, mental and social well-being. The impact of health on the quality of life has received more attention in recent years in both general and oral health. Although OHRQOL in children measurements have been used in Europe and America, they have not yet been used in non Western countries.

The aim of this study: To adapt an existing measure of Child Oral Health Related Quality of life (COHRQOL) devised in Canada for use in Saudi Arabia. Then to test the Arabic version has similar psychometric properties to the English version.

Methods: A cross-cultural adaptation of Oral Health-related Quality of Life (OHRQOL) by translation, back-translation, committee review, qualitative Interviews and pre-testing was employed.

Results: The score means and psychometric properties were similar to the original development scale in the parental and child questionnaire by Jokovic et al (2003) and Jokovic et al (2004) respectively.

Conclusions: The Arabic version of the CPQ 8-10 and P-CPQ developed in the study demonstrates cross-cultural equivalence according to the criteria provided by Guillemin et al (1993).

Appendix 20-A Cross-cultural adaptation of Oral Health Related Quality of Life, Poster Presentation in **BSDR Conference**, Glasgow, Sept 1-4. 2009

Cross cultural adaptation of a Child Oral Health Related Quality of Life measure

Abdulraof AlGhadeer, Tim Newton and Stephen Dunne
Oral Health Services Research & Dental Public Health
Corresponding contact: A. Alghadeer, Email: abdulraof.alghadeer@kcl.ac.uk

King's College London
Dental Institute
at Guy's, King's College and St Thomas' Hospitals
www.kcl.ac.uk/dentistry

1. Introduction

The key issue in the conception of Health Related Quality of Life (HRQOL) and accordingly Oral Health Related Quality of Life (OHRQOL) is the shift in the perception of health from merely the absence of disease and infirmity to complete physical, mental and social well-being in line with the definition of health, by the World Health Organisation (1). It is now widely accepted that health assessment should include the measurement of physical, social and psychological functions, and also quality of life. OHRQOL includes components such as function, pain, psychological components and social aspects (2).

OHRQOL measures have three broad purposes. First, they could be used for political purposes to demonstrate the effects of oral disorders to policy makers. Second, they can have theoretical value in developing and testing models of oral health and general health. Thirdly, the measures should be put to practical use in research to best meet our needs for planning and evaluating treatment of individuals (3). Furthermore, OHRQOL is an essential factor in oral health surveys, clinical research and studies that evaluate the outcomes of preventive and therapeutic programmes planned to improve oral health status (4, 5).

2. Objectives

- To adapt an existing measure of Child Oral Health Related Quality of life (COHRQOL) devised in Canada for use in Saudi Arabia. Then to test the psychometric properties of the Arabic version.
- To evaluate and assess the validity and reliability of the questionnaire of Oral Health-related Quality of Life in 8-10-year-old (CPQ8-10) and parental perceptions of Child Oral Health-related Quality of Life (PPQ6-14) Arabic version among Saudi children 8-10 years and their parents.
- To compare the OHRQOL of children and their parents between Saudi Arabia and UK.

3. Methods

Ethical approval for conducting the research was sought from the Directorate of Health Affaires in Alhasa, Saudi Arabia and KCH Research Committee.
The child questionnaire for measuring Oral Health-related Quality of Life in 8-10 year-old children, which was developed by Jokovic et al (2004) (6), and Parental Perceptions of Child Oral Health-related Quality of Life (Jokovic et al. 2003) (7), questionnaires were used after translating into the Arabic language by using a cross-cultural adaptation method according to the criteria provided by Guillemin et al (1993) (8).
A cross sectional epidemiological survey was undertaken in Saudi Arabia (Table 1). The Saudi Arabia sites are General Dental Practitioner Clinics at Primary Health Care centres (PHC), Paediatric Dental Clinic at Dental Centre (DC) and the Oral and Maxillofacial Department at King Fahad Hospital Hofuf in Al-hasa (KFHH). While in the UK sites will be undertaken in the Dental Institute at Denmark Hill and in Community Dental clinics.

Figure 2: Qualitative interview

Figure3: First committee group

Figure1: A cross-cultural adaptation method

	PHC	DC	Hospital	Total
No.	5	5	10	25
Male	1	3	6	10
Female	4	2	4	10
8 Y/O	2	1	4	7
9 Y/O	1	1	4	6
10 Y/O	2	3	2	7

Table1:Description of the sample size

4. Results

The results are displayed in Tables 1 and 2 and figures 4 and 5.
The scores mean and psychometric properties of the Arabic version of the CPQ 8-10 and P-CPQ developed in the Saudi study site her demonstrates cross-cultural equivalence according to the criteria provided by Guillemin et al (1993) (8).

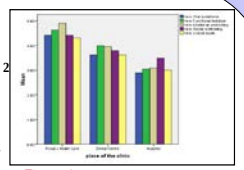


Figure 4: Distribution of P-CPQ: scale and subscales by clinical groups

The score means and psychometric properties were similar to the original development scale in the parental and child questionnaire by Jokovic ea al (2003) and Jokovic et al (2004) respectively.

Table 2 shows the statistics comparison scale and subscale scores between Saudi study and Jokovic study 8-10 years-old.

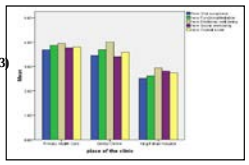


Figure 5: Distribution of CPQ 8-10, scale and subscales by clinical groups

	Jokovic study, N= 68 Mean (SD)	Saudi study, N=25 Mean (SD)	P-Value
Total scale	18.6 (12.6)	17.3 (3.2)	0.612
subscales			
Oral symptoms	5.6 (3.2)	4.1 (0.9)	0.023
Functional limitation	4.1 (3.5)	4.3 (0.96)	0.779
Emotional well-being	3.7 (3.5)	4.6 (0.72)	0.206
Social well-being	5.2 (4.7)	4.3 (0.73)	0.344

Table 2: Statistics comparison scale and subscale scores between Saudi study and Jokovic study 8-10 years-old

5. Discussion

This study was undertaken to develop a cross-cultural equivalent version of the CPQ 8-10 and P-CPQ. This was achieved by translated, back translated and a small scale study of its cultural equivalence. The equivalence of the scale was tested against the dimensions outlined by Guillemin et al(8).
Semantic equivalence was achieved by translation and back translation which agreed a stable version of the questionnaire. Idiomatic equivalence was reviewed by two independent panels of expert as well as parents and children. Experiential equivalence was established by pre-testing the questionnaire, while the conceptual equivalence was achieved by the qualitative interviews (9).

6. Conclusion

In conclusion the Arabic version of the CPQ 8-10 and P-CPQ developed in this study are valid and reliable instruments for assessing oral health-related quality of life among the child and parent respectively.

7. References

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5. McGrath C. and Bedi R Understanding the value of oral health to people in Britain - importance to life quality. Community Dental Health 2002; 19:211-214.
6. Jokovic A, Locker D, Stephens M, Kenny D, Tompson B and Guyatt G (2003): Measuring Parental Perceptions of Child oral Health-related Quality of Life. Journal of Public Health Dentistry, 63(2): 67-72.
7. Jokovic A, Locker D, Thompson B and Guyatt G (2004): Questionnaire for measuring oral health-related quality of life in eight- to ten-year-old children. Pediatr Dent., 26(6):512-8.
8. Guillemin F, Bombardier C and Beaton D. Cross-cultural Adaptation of Health-related Quality of Life: Literature Review and Proposed guidelines. J Clin. Epidemiol 1993; 46 (12): 1417-1432.
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Appendix 20-B OHRQoL in Children 8-10 in Saudi Arabia and England in **IADR 88th** General Session and Exhibition, Barcelona, Spain (July 14-17- 2010).

OHRQOL IN CHILDREN AGED 8-10 IN SAUDI ARABIA AND ENGLAND

A. ALGHADEER[1], *J.T. NEWTON*[2], *and S. DUNNE*[1], [1]*King's College London, London, United Kingdom*, [2]*King's College London, Lonodon, United Kingdom*

Background: Oral Health Related Quality (OHRQoL) measurement is an important factor in clinical practice for identifying health needs, selecting type of treatment and assessment of oral health progression. The impact of health on the quality of life has received more attention in recent years in both general and oral health. Although OHRQoL measurements in children have been used in Europe and America, they have not yet been used in non Western countries.

Objectives: To assess the validity and reliability of Arabic versions of the questionnaires CPQ8-10 and PPQ6-14 among Saudi children 8-10 years and their parent respectively. To compare the OHRQoL of children and their parents between Saudi Arabia and England. Methods: A cross sectional epidemiological survey was conducted; involving 75 children aged 8 to 10 years and their parent who attended three dental clinics in Alhasa City in Saudi Arabia. The parents were asked to complete the Parental Perception Questionnaire (PPQ). A further 75 children from a dental clinic in London and a community clinic were recruited in England. Thus, a total of 150 children were recruited.

Results: The Saudi version of the CPQ8-10 showed good internal consistency for all subscales and the total scale (all Cronbach alpha > 0.6). There were no significant differences in OHRQoL for children in the two national samples for the total scale and subscales of functional limitation and social wellbeing, P-values: 0.885, 0.179 and 0.001 respectively. But comparison of the Saudi Arabia and England parents found significant differences on the total scales and all subscales (all P-values < 0.001).

Conclusions: The Saudi Arabian version of the CPQ8-10 shows good internal consistency. While children in Saudi and England showed similar levels of OHRQoL, parents of children in England reported greater impact than parents of Saudi Arabian children.

Appendix 20-B OHRQOL in Children 8-10 in Saudi Arabia and England in **IADR 88th** General Session and Exhibition, Barcelona, Spain (July 14-17-2010).

Poster # : 1000

OHRQOL in children aged 8-10 in Saudi Arabia and England

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Poster # : 1000

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BACKGROUND AND OBJECTIVE

It is now widely accepted that health assessment should include measurement of physical, social and psychological functions, and also the quality of life. OHRQOL (oral health related quality of life) includes components such as function, pain, psychological components and social aspects (1). It is recommended that when assessing oral health outcomes and oral health need, researchers should include the psychological impact of oral health (2). OHRQOL can be used to assess dental health services, effectiveness of dental treatment and future plans for oral health needs and programmes (3). In the last two decades there has been considerable progress on the study of the oral health and quality of life for adults and children (4)

Although these measures appear in use in Europe and America, they have not yet been used in non Western countries. Therefore there is a need for research and precise studies of the impact on children in non Western countries of OHRQOL. Thus the aims of this study were to evaluate and assess the validity and reliability of the Questionnaire CPQ8-10 and PPQ6-14 Arabic version among Saudi children 8-10 years and their parents respectively.

METHODS & MATERIALS

Study one:
This study was undertaken to develop a cross-cultural equivalent version of the CPQ 8-10 and P-CPQ of The child questionnaire which was developed by Jokovic et al (2004) (5), and Parental Perceptions of Child Oral Health-related Quality of Life (Jokovic et al. 2003) (6).
This was achieved by translated, back translated, committee review, pre-test, second committee and second pre-test (Figure: 1).
The equivalence of the scale was tested against the dimensions outlined by Guillemin et al (1993) (7).

Site of the Clinic	Number of children	Total
Saudi Arabia: 1. Primary Health care 2. Hospital (KFHH) 3. Dental Centre	25 25 25	75
England: 1. Hospital- Paediatric 2. Hospital- Peadiatric, casualty 3.Community Peadodontic clinic	25 25 25	75

Table 1: subject group

Translation → Back translation → Committee review → Qualitative interview → Pre-testing the scale

Figure 1: cross-cultural adaptation

METHODS & MATERIALS

Study two:
Psychometric properties of the scales
A small scale cross sectional epidemiological survey was undertaken in Saudi Arabia and England.

Subject group
A consecutive series of 75 Children aged 8 to 10 years and their parents who attend the three dental clinics in Saudi Arabia were recruited. The parents of children were asked to complete the Parental Perception Questionnaire (PPQ). A further 75 children from the Dental clinic in England site were recruited (**Table: 1**).

RESULTS

Descriptive statistic (Table 2)
Table 2 represent the overall scores of total scales and subscales for Saudi Arabia and England. There were no significant differences in OHRQOL for children and parent's questionnaires in the two national samples (all p-values > 0.05) except in the subscale of social well-being in the child questionnaire the comparison found a significant difference (p-value= 0.018).
Discriminant validity (Table 3)
As expected in the Saudi Arabia location study the overall mean scores was higher in the hospital group and lower in the PHC group for children and parental questionnaires with p-value = 0.002 and 0.009 respectively.

	Saudi Arabia	England	
Child questionnaires	**Mean (SD)**	**Mean (SD)**	**P-value**
Total scale	15.76 (11.16)	13.83 (12.57)	0.32
subscale			
Oral symptoms	5.00 (3.38)	5.04 (3.47)	0.95
Functional limitation	3.15 (3.34)	2.91 (3.60)	0.67
Emotional well-being	2.97 (3.33)	2.77 (3.83)	0.73
Social well-being	4.64 (3.75)	3.11 (4.07)	0.018
Parent questionnaires			
Total scale	21.05 (14.02)	19.24 (14.39)	0.43
subscale			
Oral symptoms	6.71 (4.26)	6.19 (4.26)	0.45
Functional limitation	5.79 (5.24)	5.37 (5.37)	0.62
Emotional well-being	3.24 (3.13)	2.87 (2.83)	0.44
Social well-being	5.32 (4.95)	4.81 (4.97)	0.52

Table 2: Descriptive statistic

Scale scores	Mean (SD)	Mean (SD)	Mean (SD)	P*- Sig.
Saudi site	PHC (N= 25)	Dental Centre (N= 25)	Hospital (N= 25)	
Total scale For children	10.12 (6.88)	16.28 (10.70)	20.88 (12.71)	0.002
Total scale For Parent	16.28 (8.33)	19.16 (13.92)	27.72 (16.38)	0.009
England site	Community clinic	(paediatric dental clinic)	(casualty clinic)	
Total scale For children	8.00 (7.65)	15.36 (13.68)	18.12 (13.97)	0.031
Total scale For Parent	12.32 (7.36)	18.92 (14.56)	26.68 (16.37)	0.001

Table 3: Discriminant validity

Scale scores	Oral health		Overall well-being	
	R	P	R	P
Total scale for Saudi child	0.33	< 0.05= 0.765	0.21	< 0.05= 0.06
Total scale for Saudi Parent	0.26	< 0.05= 0.023	0.18	< 0.05= 0.123
Total scale for England child	0.37	< 0.05= 0.004	0.55	< 0.01= 0.000
Total scale for England Parent	0.35	< 0.05= 0.002	0.29	< 0.05= 0.01

Table 5: Construct validity

Children Q	No. of items	Cronbach's alpha (N= 75)	Intraclass correlation coefficient (N= 75)
Saudi Child. Total scale	25	0.86	0.85
Saudi Parent. Total scale	31	0.90	0.89
England Child. Total scale	25	0.91	0.89
England Parent. Total scale	31	0.91	0.89

Table 4: Reliability

RESULTS

Reliability (Table 4) overall the Internal consistency and Intraclass Correlation Coefficient (ICC) for CPQ8-10 and PCPQ in both nationalities were acceptable. Cronbach's alpha for the overall scale in Saudi and England (> 0.86) indicated an excellent internal consistency in children and their parents. However Cronbach's alpha for subscales ranged between 0.45 and 0.85 indicating as moderate to high internal consistency.
Construct validity (Table 5) Spearman's correlation between global rating indicators and the Saudi CPQ 8-10 (children) for overall scale and subscales were not significant (all p-value>0.05) and it ranged from low to moderate.
In the England study the correlation between global indicators and the CPQ 8-10 was positive and significant for overall and subscales. However the Spearman's Correlation for the P-CPQ was a positive correlation and significant in overall scales and global ratings for oral health

CONCLUSIONS

1.The Arabic version which was developed in study one can be used for assessing OHRQOL for children 8-10 and their parents in Arabic countries
2.The Saudi Arabian version of the CPQ 8-10 shows good internal consistency.
3.While children in Saudi and England showed similar levels of OHRQOL, parents of English children reported greater impact than parents of Saudi Arabian children.
4. A prospective research on a sample size would be recommended in future studies. In order to assess change of oral health status and OHRQOL over time.

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Appendix 20-C Development and Validation of Arabic version of CPQ8-10 in **IADR 89th** General Session and Exhibition, San Diego, USA (March 16-19- 2011).

DEVELOPMENT AND VALIDATION OF AN ARABIC VERSION OF CPQ8-10

Thursday, March 17, 2011: 3:30 p.m. - 4:45 p.m.
Location: Room 5B (San Diego Convention Center)
Presentation Type: Poster Discussion Session

***A. ALGHADEER**, Oral Health Services Research & Dental Public Health, King's College London, London, United Kingdom, S. DUNNE, Primary Dental Care, King's College London Dental Institute, London, United Kingdom, and J.T. NEWTON, Oral Health Services Reseach & Dental Public Health, King's College London Dental Institute, London, United Kingdom*

Objectives: To assess the validity and reliability of Arabic versions of the questionnaires Oral Health-related Quality of Life in 8-10-year-old (CPQ8-10) (Jokovic et al, 2003) and Parental Perceptions of Child Oral Health-related Quality of Life (PPQ6-14) (Jokovic et al, 2004) among Saudi children 8-10 years and their parents respectively.

Methods: Culturally equivalent Arabic forms of the CPQ8-10 and PPQ6-14 were created following the guidelines Guillemin et al (1993). Seventy five children aged 8 to 10 years and their parents attending three dental clinics in Alhasa City in Saudi Arabia, completed the questionnaires.

Results: The Arabic version in this study of the CPQ8-10 showed good internal consistency for all subscales and the total scale (all Cronbach's alpha > 0.50). discriminant validity was confirmed with the overall mean scores was higher in the hospital group and lower in the PHCC. Spearman's Correlation between global rating indicators and overall scale and subscales were not significant (all p-value > 0.05).

Conclusions: The Arabic version of the CPQ8-10 shows good internal consistency. In order to assess the change of oral health status and quality of life over time, a Prospective research on a sample size would be recommended in future studies.

Appendix 20-C Development and Validation of Arabic version of CPQ8-10 in **IADR 89th** General Session and Exhibition, San Diego, USA (March 16-19- 2011).

Oral Health related Quality of Life in children aged 8-10 in Saudi Arabia and England

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BACKGROUND AND OBJECTIVES

❖ **The key issue in the conception of HRQOL (Health Related Quality of Life) and accordingly Oral Health Related Quality of Life (OHRQOL) is the shift in the perception of health from merely the absence of disease and infirmity to complete physical, mental and social well-being in line with the definition of 'Health by World Health Organisation (WHO, 1948).**

❖ **It is now widely accepted that health assessment should include measurement of physical, social and psychological functions, and also the quality of life. OHRQOL includes components such as function, pain, psychological components and social aspects (Locker, 1988).**

❖ **Aims of the study: To evaluate and assess the validity and reliability of the Questionnaire CPQ8-10 and PPQ6-14 Arabic version among Saudi children 8-10 years and their parent respectively.**
To compare the OHRQOL of children and their parents between Saudi Arabia and UK.

MATERIALS AND METHODS

❖ ***Study one:*** **This study was undertaken to develop a cross-cultural equivalent version of the CPQ 8-10 and P-CPQ of The child questionnaire which was developed by Jokovic et al (2004) (5), and Parental Perceptions of Child Oral Health-related Quality of Life (Jokovic et al. 2003) (6).**
This was achieved by translated, back translated, committee review, pre-test, second committee and second pre-test (Figure: 1).
The equivalence of the scale was tested against the dimensions outlined by Guillemin et al (1993) (7).

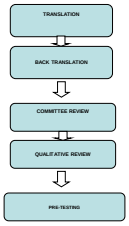

Figure1: **A cross-cultural adaptation method**

Site of the Clinic	Number of children	Total
Saudi Arabia: **1. Primary Health care** **2. Hospital (KFHH)** **3. Dental Centre**	25 25 25	75
England: **1. Hospital- Paediatric** **2. Hospital- Peadiatric, casualty** **3.Community Peadodontic clinic**	25 25 25	75

Table 1:**Description of the sample size**

❖ ***Study two:*** ***Psychometric properties of the scales,*** **A small scale cross sectional epidemiological survey was undertaken in Saudi Arabia and England.**
Subject group: **A consecutive series of 75 Children aged 8 to 10 years and their parents who attend the three dental clinics in Saudi Arabia were recruited. The parents of children were asked to complete the Parental Perception Questionnaire (PPQ). A further 75 children from the Dental clinic in England site were recruited (Table 1)**

RESULTS

I. Overall scales and subscales for Saudi Arabia and England

Table 2 represent the overall scores of total scales and subscales for Saudi Arabia and England. There were no significant differences in OHRQOL for children and parent's questionnaires in the two national samples (all p > 0.05) except in the subscale of social well-being in the child questionnaire the comparison found a significant difference (p= 0.018).

	Saudi Arabia	England	
Child questionnaires	**Mean (SD)**	**Mean (SD)**	**p**
Total scale	15.76 (11.16)	13.83 (12.57)	0.32
subscale			
Oral symptoms	5.00 (3.38)	5.04 (3.47)	0.95
Functional limitation	3.15 (3.34)	2.91 (3.00)	0.67
Emotional well-being	2.97 (3.33)	2.77 (3.83)	0.73
Social well-being	4.64 (3.75)	3.11 (4.07)	0.018
Parent questionnaires			
Total scale	21.05 (14.02)	19.24 (14.39)	0.43
subscale			
Oral symptoms	6.71 (4.26)	6.19 (4.26)	0.45
Functional limitation	5.79 (5.24)	5.37 (5.37)	0.62
Emotional well-being	3.24 (3.13)	2.87 (2.83)	0.44
Social well-being	5.32 (4.95)	4.81 (4.97)	0.52

Table 2:**Description of the sample size**

RESULTS

II. Discriminant validity

Scale scores	Community clinic	Dental Hospital (paediatric dental clinic)	Dental Hospital (casualty clinic)	F	p
For children	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**		
Total scale (overall scale)	**8.00 (7.05)**	**15.36 (13.60)**	**18.12 (13.97)**	**4.78**	**0.011**
Subscales					
Oral symptoms	**4.00 (3.29)**	**5.36 (3.24)**	**5.76 (3.83)**	**1.81**	**0.172**
Functional limitation	**1.32 (1.87)**	**2.88 (3.48)**	**4.52 (4.35)**	**5.56**	**0.006**
Emotional well-being	**1.28 (2.44)**	**3.48 (4.46)**	**3.56 (3.57)**	**3.02**	**0.055**
Social well-being	**1.40 (1.47)**	**3.64 (5.35)**	**4.28 (3.90)**	**3.73**	**0.029**
For parent					
Total scale (overall scale)	**12.12 (7.36)**	**18.92 (14.36)**	**26.68 (16.37)**	**7.54**	**0.001**
Subscales					
Oral symptoms	**4.52 (3.11)**	**6.52 (4.46)**	**7.52 (4.65)**	**3.42**	**0.038**
Functional limitation	**3.20 (3.08)**	**5.28 (6.10)**	**7.64 (5.64)**	**4.71**	**0.012**
Emotional well-being	**2.04 (1.69)**	**3.16 (3.11)**	**3.40 (3.33)**	**1.68**	**0.195**
Social well-being	**2.36 (2.93)**	**3.96 (4.18)**	**8.12 (5.63)**	**11.49**	**< 0.001**

Table 3: Saudi sample

Scale scores	PHC (N= 25)	Dental Centre (N= 25)	Hospital (N= 25)		
For children	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**	**F**	**p**
Total scale (overall scale)	**10.12 (6.88)**	**16.28 (10.70)**	**20.88 (12.71)**	**6.70**	**0.002**
Subscales					
Oral symptoms	**3.88 (2.83)**	**5.36 (3.23)**	**5.76 (3.83)**	**2.22**	**0.116**
Functional limitation	**1.80 (1.95)**	**2.92 (2.72)**	**4.72 (4.32)**	**5.45**	**0.006**
Emotional well-being	**1.92 (2.50)**	**3.36 (4.01)**	**3.64 (3.17)**	**1.97**	**0.147**
Social well-being	**2.52 (1.92)**	**4.64 (3.79)**	**6.76 (4.00)**	**9.90**	**< 0.001**
For parent					
Total scale (overall scale)	**16.28 (8.33)**	**19.16 (13.93)**	**27.72 (16.38)**	**4.99**	**0.009**
Subscales					
Oral symptoms	**5.64 (3.53)**	**6.88 (4.36)**	**7.60 (4.72)**	**1.37**	**0.261**
Functional limitation	**4.48 (3.59)**	**5.04 (5.58)**	**7.84 (5.89)**	**3.12**	**0.050**
Emotional well-being	**2.48 (1.78)**	**3.24 (3.14)**	**4.00 (4.32)**	**1.49**	**0.232**
Social well-being	**3.68 (3.95)**	**4.60 (4.19)**	**8.28 (5.35)**	**7.99**	**0.001**

Table 4: **England sample**

III. Reliability

	Children		Parent	
	No. of items	**Cronbach's alpha (N= 75)**	**No. of items**	**Cronbach's alpha (N= 75)**
Total scale (overall scale)	25	**0.86**	31	**0.90**
Subscales				
Oral symptoms	5	**0.65**	6	**0.66**
Functional limitation	5	**0.74**	8	**0.78**
Emotional well-being	5	**0.75**	7	**0.50**
Social well-being	10	**0.56**	10	**0.85**

Table Saudi sample

	Children		Parent	
	No. of items	**Cronbach's alpha (N= 75)**	**No. of items**	**Cronbach's alpha (N= 75)**
Total scale (overall scale)	25	**0.91**	31	**0.91**
Subscales				
Oral symptoms	5	**0.68**	6	**0.74**
Functional limitation	5	**0.77**	8	**0.82**
Emotional well-being	5	**0.83**	7	**0.46**
Social well-being	10	**0.79**	10	**0.85**

Table 6: **England sample**

VI. Construct Validity- Rank Correlation between Scores and Global ratings of Oral Health and Overall Well-being

Scale scores	Oral health		Overall well-being	
Saudi child	**rho**	**p**	**rho**	**p**
Total scale (overall scale)	**0.13**	**0.765**	**0.21**	**0.06**
Subscales				
Oral symptoms	**0.13**	**0.91**	**0.24**	**0.038**
Functional limitation	**0.11**	**0.399**	**0.16**	**0.152**
Emotional well-being	**0.10**	**0.552**	**0.11**	**0.396**
Social well-being	**0.11**	**0.361**	**0.18**	**0.134**
Saudi Parent	**rho**	**p**	**rho**	**p**
Total scale (overall scale)	**0.26**	**0.023**	**0.18**	**0.123**
Subscales				
Oral symptoms	**0.15**	**0.146**	**0.05**	**0.048)**
Functional limitation	**0.30**	**0.01)**	**0.11**	**0.355**
Emotional well-being	**0.12**	**0.033**	**0.14**	**0.550**
Social well-being	**0.27**	**0.021**	**0.23**	**0.05**

Table 7: **Saudi sample**

Scale scores	Oral health		Overall well-being	
Child	**rho**	**p**	**rho**	**p**
Total scale (overall scale)	**0.37**	**0.001**	**0.55**	**< 0.001**
Subscales				
Oral symptoms	**0.35**	**0.002**	**0.52**	**< 0.001**
Functional limitation	**0.28**	**0.015**	**0.36**	**0.001**
Emotional well-being	**0.36**	**0.001**	**0.51**	**> 0.001**
Social well-being	**0.24**	**0.038**	**0.48**	**> 0.001**
Parent	**rho**	**p**	**rho**	**p**
Total scale (overall scale)	**0.35**	**0.002**	**0.29**	**0.01**
Subscales				
Oral symptoms	**0.29**	**0.012**	**0.18**	**0.104**
Functional limitation	**0.34**	**0.003**	**0.21**	**0.038**
Emotional well-being	**0.13**	**0.312**	**0.11**	**0.469**
Social well-being	**0.39**	**< 0.001**	**0.39**	**< 0.001**

Table **England sample**

CONCLUSIONS

❖ **The Arabic version which was developed in study one can be used for assessing OHRQOL for children 8-10 and their parents in Arabic countries.**
❖ **The Saudi Arabian version of the CPQ 8-10 shows good internal consistency.**
❖ **While children in Saudi and England showed similar levels of OHRQOL, parents of English children reported greater impact than parents of Saudi Arabian children.**
❖ **A prospective research on a sample size would be recommended in future studies. In order to assess change of oral health status and OHRQOL over time.**

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Appendix 20-D Oral Health related Quality of Life in children aged 8-10 in Saudi Arabia and England in **BSDR**, Sheffield, UK (12-15 September 2011)

Oral Health related Quality of Life in children aged 8-10 in Saudi Arabia and England

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BACKGROUND AND OBJECTIVES

❖ **The key issue in the conception of HRQOL (Health Related Quality of Life) and accordingly Oral Health Related Quality of Life (OHRQOL) is the shift in the perception of health from merely the absence of disease and infirmity to complete physical, mental and social well-being in line with the definition of 'Health by World Health Organisation (WHO, 1948).**

❖ **It is now widely accepted that health assessment should include measurement of physical, social and psychological functions, and also the quality of life. OHRQOL includes components such as function, pain, psychological components and social aspects (Locker, 1988).**

❖ **Aims of the study: To evaluate and assess the validity and reliability of the Questionnaire CPQ8-10 and PPQ6-14 Arabic version among Saudi children 8-10 years and their parent respectively.**

To compare the OHRQOL of children and their parents between Saudi Arabia and UK.

MATERIALS AND METHODS

❖ ***Study one:*** **This study was undertaken to develop a cross-cultural equivalent version of the CPQ 8-10 and P-CPQ of The child questionnaire which was developed by Jokovic et al (2004) (5), and Parental Perceptions of Child Oral Health-related Quality of Life (Jokovic et al. 2003) (6).**

This was achieved by translated, back translated, committee review, pre-test, second committee and second pre-test (Figure: 1).

The equivalence of the scale was tested against the dimensions outlined by Guillemin et al (1993) (7).

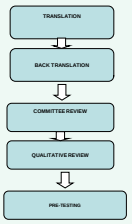

Figure1: **A cross-cultural adaptation method**

Site of the Clinic	Number of children	Total
Saudi Arabia: 1. Primary Health care 2. Hospital (KFHH) 3. Dental Centre	 25 25 25	75
England: 1. Hospital- Paediatric 2. Hospital- Peadiatric, casualty 3.Community Peadodontic clinic	 25 25 25	75

Table 1:**Description of the sample size**

❖ ***Study two:*** ***Psychometric properties of the scales,*** **A small scale cross sectional epidemiological survey was undertaken in Saudi Arabia and England.**

Subject group: **A consecutive series of 75 Children aged 8 to 10 years and their parents who attend the three dental clinics in Saudi Arabia were recruited. The parents of children were asked to complete the Parental Perception Questionnaire (PPQ). A further 75 children from the Dental clinic in England site were recruited (Table 1)**

RESULTS

I. Overall scales and subscales for Saudi Arabia and England

Table 2 represent the overall scores of total scales and subscales for Saudi Arabia and England. There were no significant differences in OHRQOL for children and parent's questionnaires in the two national samples (all p > 0.05) except in the subscale of social well-being in the child questionnaire the comparison found a significant difference (p= 0.018).

	Saudi Arabia	England	
Child questionnaires	Mean (SD)	Mean (SD)	p
Total scale	15.76 (11.16)	13.83 (12.57)	0.32
subscale			
Oral symptoms	5.00 (3.38)	5.04 (3.47)	0.35
Functional limitation	3.15 (3.34)	2.91 (3.60)	0.67
Emotional well-being	2.97 (3.33)	2.77 (3.83)	0.71
Social well-being	4.64 (3.75)	3.11 (4.07)	0.018
Parent questionnaires			
Total scale	21.05 (14.02)	19.24 (14.39)	0.43
subscale			
Oral symptoms	6.71 (4.26)	6.19 (4.26)	0.45
Functional limitation	5.79 (5.24)	5.37 (5.37)	0.62
Emotional well-being	3.24 (5.13)	2.87 (2.83)	0.44
Social well-being	5.32 (4.95)	4.81 (4.97)	0.52

Table 2:**Description of the sample size**

RESULTS

II. Discriminant validity

Scale scores	Community clinic	Dental Hospital (paediatric dental clinic)	Dental Hospital (casualty clinic)	F	p
For children	Mean (SD)	Mean (SD)	Mean (SD)		
Total scale (overall scale)	8.00 (7.05)	15.36 (13.60)	18.12 (13.97)	4.78	0.011
Subscales					
Oral symptoms	4.00 (3.29)	5.36 (3.24)	5.76 (3.83)	1.81	0.172
Functional limitation	1.32 (1.87)	2.88 (1.48)	4.52 (4.35)	5.56	0.006
Emotional well-being	1.28 (2.66)	3.48 (4.46)	3.56 (3.97)	3.02	0.055
Social well-being	1.40 (1.47)	3.64 (5.35)	4.28 (3.90)	3.73	0.029
For parent					
Total scale (overall scale)	12.12 (7.36)	18.92 (14.36)	26.68 (16.37)	7.54	0.001
Subscales					
Oral symptoms	4.52 (3.11)	6.52 (4.46)	7.52 (4.65)	3.42	0.038
Functional limitation	3.20 (3.08)	5.28 (6.10)	7.64 (5.64)	4.71	0.012
Emotional well-being	2.04 (1.69)	3.16 (3.11)	3.40 (3.33)	1.68	0.195
Social well-being	2.36 (2.93)	3.96 (4.18)	8.12 (5.63)	11.49	< 0.001

Table 3: Saudi sample

Scale scores	PHC (N= 25)	Dental Centre (N= 25)	Hospital (N= 25)		
For children	Mean (SD)	Mean (SD)	Mean (SD)	F	p
Total scale (overall scale)	10.12 (6.88)	16.28 (10.70)	20.88 (12.71)	6.76	0.002
Subscales					
Oral symptoms	3.88 (2.83)	5.36 (3.23)	5.76 (3.83)	2.22	0.116
Functional limitation	1.80 (1.95)	2.92 (2.72)	4.72 (4.32)	5.45	0.006
Emotional well-being	1.92 (2.50)	3.36 (4.01)	3.64 (3.17)	1.97	0.147
Social well-being	2.52 (1.52)	4.64 (3.79)	6.76 (4.88)	9.98	< 0.001
For parent					
Total scale (overall scale)	16.28 (8.13)	19.16 (13.93)	27.72 (16.38)	4.99	0.009
Subscales					
Oral symptoms	5.64 (3.53)	6.88 (4.36)	7.60 (4.72)	1.37	0.261
Functional limitation	4.48 (3.59)	5.04 (5.58)	7.84 (5.89)	3.12	0.050
Emotional well-being	2.48 (1.78)	3.24 (3.14)	4.00 (4.32)	1.49	0.232
Social well-being	3.68 (3.95)	4.00 (4.19)	8.28 (5.35)	7.99	0.001

Table 4: **England sample**

III. Reliability

	Children		Parent	
	No. of items	Cronbach's alpha (N= 75)	No. of items	Cronbach's alpha (N= 75)
Total scale (overall scale)	25	0.86	31	0.90
Subscales				
Oral symptoms	5	0.65	6	0.66
Functional limitation	5	0.74	8	0.78
Emotional well-being	5	0.75	7	0.59
Social well-being	10	0.56	10	0.85

Table Saudi sample

	Children		Parent	
	No. of items	Cronbach's alpha (N= 75)	No. of items	Cronbach's alpha (N= 75)
Total scale (overall scale)	25	0.91	31	0.91
Subscales				
Oral symptoms	5	0.68	6	0.74
Functional limitation	5	0.77	8	0.82
Emotional well-being	5	0.83	7	0.46
Social well-being	10	0.79	10	0.85

Table 6: **England sample**

VI. Construct Validity- Rank Correlation between Scores and Global ratings of Oral Health and Overall Well-being

Scale scores	Oral health		Overall well-being	
Saudi child	rho	p	rho	p
Total scale (overall scale)	0.13	0.765	0.21	0.06
Subscales				
Oral symptoms	0.13	0.91	0.24	0.038
Functional limitation	0.11	0.399	0.16	0.152
Emotional well-being	0.10	0.552	0.11	0.396
Social well-being	0.11	0.361	0.18	0.134
Saudi Parent	rho	p	rho	p
Total scale (overall scale)	0.26	0.023	0.18	0.123
Subscales				
Oral symptoms	0.15	0.146	0.05	0.040)
Functional limitation	0.30	0.01)	0.11	0.355
Emotional well-being	0.12	0.033	0.14	0.550
Social well-being	0.27	0.021	0.23	0.05

Table 7: Saudi sample

Scale scores	Oral health		Overall well-being	
Child	rho	p	rho	p
Total scale (overall scale)	0.37	0.001	0.55	< 0.001
Subscales				
Oral symptoms	0.35	0.002	0.52	< 0.001
Functional limitation	0.28	0.015	0.36	0.001
Emotional well-being	0.36	0.001	0.51	> 0.001
Social well-being	0.24	0.038	0.48	> 0.001
Parent	rho	p	rho	p
Total scale (overall scale)	0.35	0.002	0.29	0.01
Subscales				
Oral symptoms	0.29	0.012	0.18	0.104
Functional limitation	0.34	0.003	0.21	0.038
Emotional well-being	0.13	0.912	0.11	0.469
Social well-being	0.39	< 0.001	0.39	< 0.001

Table **England sample**

CONCLUSIONS

❖ **The Arabic version which was developed in study one can be used for assessing OHRQOL for children 8-10 and their parents in Arabic countries.**

❖ **The Saudi Arabian version of the CPQ 8-10 shows good internal consistency.**

❖ **While children in Saudi and England showed similar levels of OHRQOL, parents of English children reported greater impact than parents of Saudi Arabian children.**

❖ **A prospective research on a sample size would be recommended in future studies. In order to assess change of oral health status and OHRQOL over time.**

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Apendix 20-E Cross Cultural Adaptation of Oral Health-Related Quality of Life Measures, Published in ***Dental Update*** Journal in December 2010; **37**: 706-708.

Abdulraof Alghadeer
Tim Newton and Stephen Dunne

Cross Cultural Adaptation of Oral Health-Related Quality of Life Measures

Abstract: Oral Health-Related Quality of Life (OHRQOL) is the shift in the perception of health from merely the absence of disease and infirmity to complete physical, mental and social well-being. The impact of health on the quality of life has received more attention in recent years in both general and oral health. OHRQOL assessments are used in oral health research, surveys and studies evaluating the outcome of oral care.

If researchers have no appropriate health-related quality of life (HRQOL) measure in their own language, they have two options: to develop a new measure or to modify a measure that has previously been validated in another language which is known as a cross-cultural adaptation process. The aim of this study is to provide guidance on how to adapt an existing measure of Oral Health-Related Quality of Life (OHRQOL) for a different culture.

Clinical Relevance: It is important that dental professionals should have sufficient knowledge about Oral Health-Related Quality of Life in order to make sure that providing the treatment focuses on the patient rather than the disease. In addition, information about a patient's OHRQOL will make decisions on treatment plans which are more likely to influence clinical outcomes.

Dent Update 2010; 37: 706–708

The key issue in the conception of Health-Related Quality of Life (HRQOL) and, accordingly, Oral Health-Related Quality of Life (OHRQOL) is the shift in the perception of health from merely the absence of disease and infirmity to complete physical, mental and social well-being in line with the definition of 'Health by the World Health Organization'.[1] It is now widely accepted that health assessment should include measurement of physical, social and psychological functions, and also the quality of life. OHRQOL includes components such as function, pain, psychological components and social aspects.[2]

OHRQOL measures have three broad purposes:

- They could be used for political purposes to demonstrate the effects of oral disorders to policy makers.
- They can have theoretical value in developing and testing models of oral health and general health.
- The measures should be put to practical use in research to best meet our needs for planning and evaluating treatment of individuals.[3]

Furthermore, OHRQOL is an essential factor in oral health surveys, clinical research and studies that evaluate the outcomes of preventive and therapeutic programmes planned to develop the oral health status.[4,5]

Strategies of cross cultural adaptation

If researchers have no appropriate health-related quality of life (HRQOL) measure in their own language, they have two options:

- To develop a new measure; or
- To modify a measure that has been previously validated in another language which is known as 'cross-cultural adaptation'.[6] To develop a new measure is time consuming, while the direct translation from its original version is unlikely to be successful because of the different language and culture between the two populations. In addition, the perceptions of QOL and the impact of health problems differ from culture to culture. Direct translation of a questionnaire does not ensure that it is valid as the original questionnaire may include items which are misunderstood in the new population.[7] In order to overcome this issue, researchers should adopt particular methods in the

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Target population	Situations	Recommended process
1. Same population	In the same language, culture and country	Use the same questionnaire
2. Established immigrants	In different culture but same language and country	Need cultural adaptation
3. Another country but with the same language	Same language but different culture and country	Need cultural adaptation
4. New immigrant	Same country but different culture and language	Need translation and cultural adaptation
5. Different population	Different culture, language and country	Need translation and cultural adaptation

Table 1. The five different settings for cross-cultural adaptation of OHRQOL.

cultural adaptation of questionnaires, in particular measures of OHRQOL.

At the present time many HRQOL instruments reviewed have been used cross culturally for many years, for example, the Nottingham Health Profile (NHP) and Sickness Impact Profile (SIP). The adaptation processes are usually either included in the development stage, such as the Quality of Life Questionnaire of the EuroQOL and World Health Organization Quality of Life instrument (WHOQOL), or takes place after the development and validation of the scale, for example, the Short Form 36 (SF-36) and the Duke Health Profile (DHP).[8]

Cross-cultural adaptations could be considered for several situations (Table 1). There are five different situations:

- The questionnaire is to be used in the same population with the same culture and language in which it was developed: in this case, no translation or adaptation is needed.
- It is used in the same country with the same language but with a different culture, such as immigrant people: in this case adaptation is required but there is no need for translation.
- When the questionnaire is to be used in another country with the same language, there is no need for translation but only a need for culture adaptation.
- When the questionnaire is used in the same country but with new immigrants, translation and culture adaptation will be needed for the questionnaire.
- When the application of the questionnaire is in a different culture, language and country: in this case translation and culture adaptation would be necessary.[9,10]

According to Guillemin *et al*[6] and Herdman *et al*,[7] in order to obtain an effective and practical cross-cultural adaptation of a HRQOL measure it is necessary to ensure semantic, idiomatic, experience and conceptual equivalence of the new form. This is achieved through a process of translation, back translation, committee review, pre-test and weighting scores. A literature review by Acquadro *et al*[10] identified the common methods to be used to translate Health-Related Quality of Life questionnaires for use in different populations from where it was originated. They recommend that, in order to adapt the questionnaire, researchers should follow a multi-step method.

Guidelines for cross-cultural adaptation of OHRQOL

In this review we will focus on the guidelines proposed by Beaton *et al*[9] and Guillemin *et al* because they were the first to propose an extensive review of cross-cultural adaptation in 1993.[6] Also, it is the method currently used by the American Association of Orthopaedic Surgeons (AAOS).[9]

Forward translation

The first stage in adaptation is forward translation by at least two independent translators. The translation should be made from the original language to the target language. Bilingual translators whose mother tongue is the target language should produce the independent translation. The translators should have a different profile and background. For example, one of the translators should be informed of the concepts being covered by the questionnaire and should have a medical background. Then each translator should write a report of the translation that they complete. The report should summarize all difficulties encountered, choices made or remaining uncertainties.

Synthesis of the translations

All translators and a recording observer sit down to synthesize the results of the translations. Working from the original questionnaire with translation versions, a synthesis of the translations is first conducted to produce one common translated version. In addition, a written report should document all issues addressed and how they were resolved.

Back translation

At this stage, working from the translated version of the questionnaire and totally blind to the original version, a translator should translate the questionnaire back to the original language. This stage is a process of validity checking to make sure that the translated version reflects the same items in the original versions. This step also defines unclear wording in the translations. At least two back translators are required and they should produce a written report.

Committee review

The composition of this committee is very important to produce a cross-cultural equivalence. This should be composed of methodologists, health professionals, language professionals and all the translators including forward translators and back translators. The original

developers of the questionnaire should be in close contact with this committee. The committee will review all translations and reach an agreement on any inconsistency.

This expert report committee is making critical decisions; therefore a written report should be made of the issues and the proposed decision about them. A decision will need to be made by the committee in order to achieve equivalence between the source and target version of the questionnaire in four areas:[7]

- Semantic: this means do the words give the same meaning to a given item; also it includes grammatical difficulties in the translation.
- Idiomatic: the committee may have to formulate an equivalent expression in the final version.
- Experiential: the questionnaire item should be replaced by a similar item that is in fact experienced in the target culture.
- Conceptual: the concept explored should be valid in the target culture. The committee should examine the source and back translated questionnaires for all these equivalences. Items, instructions and response options must be measured.

Pre-test

This stage is to check the equivalence in the source and final version. Ideally, 30–40 individuals should be tested. Each participant should complete the questionnaire and be interviewed about the meaning of each item. The distribution of responses should be examined to check the proportion of any missing items. This stage will provide an evaluation of the content validity.

Co-ordinating committee for appraisal of the adaptation process

The final stage in the adaptation process is submission of all reports and forms to the developer of the instrument or the committee keeping track of the translated version. This is a process to ensure that all steps have been performed and fully documented.

Conclusion

In conclusion, the adaptation of an existing questionnaire to a different culture, as described above, has several advantages:

- It provides a common measure for investigation of HRQOL within different cultures;
- It offers a standard measure for use in international studies;
- It allows one to compare between different groups on a standard measure;
- It allows the inclusion of immigrants, avoiding the frequent bias of representing only the dominant culture; and
- It is less costly and time-consuming than generating a new measure.

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Abstract

PLEASE CONSIDER THIS VERY, VERY SENSIBLE EDITORIAL!

Endodontics versus single-tooth implants. Editorial. Richard Hermann. *Int J Periodont Rest Dent* 2010; **30**: 5

I have not written a summary of an editorial before, but this one just begged to be shared far more widely. Over recent years there has been a significant move among practitioners to assume that a root-filled tooth has a poorer prognosis than an implant, and many teeth have been extracted that could have been preserved with correct and proper endodontic treatment. Many papers have been published to support this thesis, for example from the American Academy of Implant Dentistry in Chicago, a press release entitled 'Why save bad teeth? Dental heroics unnecessary and failure prone'.

Richard Hermann presents a brief but compelling review of the evidence to show quite clearly that the statistics used are at best misleading and at worst untrue. Recent advances in root canal treatment, such as the surgical operating microscope, rotary NiTi instrumentation, ultrasonics, MTA, bioceramics and microsurgical instrumentation, have led to a position whereby the prognosis for both treatment modalities is the same, whereas implants require more postoperative treatment than endodontically-treated teeth. Furthermore, a misplaced implant may result in an aesthetic outcome that would never happen with a naturally placed root treated tooth. He concludes 'The preservation and treatment of periapical disease is paramount to saving an endodontically compromised tooth, whereas implants simply replace missing teeth.'

Don't allow misinformation to instigate the possibility of patient mistreatment.

Peter Carrotte
Glasgow